



## Clinical trial results:

### A Phase 1/2 First-in-Human Study of BMS-986249 Alone and in Combination with Nivolumab in Advanced Solid Tumors

#### Summary

|                          |                   |
|--------------------------|-------------------|
| EudraCT number           | 2018-000416-21    |
| Trial protocol           | ES DE PL FI IT RO |
| Global end of trial date | 07 November 2024  |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 22 November 2025 |
| First version publication date | 22 November 2025 |

#### Trial information

##### Trial identification

|                       |           |
|-----------------------|-----------|
| Sponsor protocol code | CA030-001 |
|-----------------------|-----------|

##### Additional study identifiers

|                                    |   |
|------------------------------------|---|
| ISRCTN number                      | - |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN)   | - |

Notes:

#### Sponsors

|                              |                                                                              |
|------------------------------|------------------------------------------------------------------------------|
| Sponsor organisation name    | Bristol-Myers Squibb                                                         |
| Sponsor organisation address | Chaussée de la Hulpe 185, Brussels, Belgium, 1170                            |
| Public contact               | Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, mg-gsm-ct@bms.com |
| Scientific contact           | Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, mg-gsm-ct@bms.com |

Notes:

#### Paediatric regulatory details

|                                                                      |    |
|----------------------------------------------------------------------|----|
| Is trial part of an agreed paediatric investigation plan (PIP)       | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

|                                                      |                  |
|------------------------------------------------------|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 07 November 2024 |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 07 November 2024 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

To characterize the safety, tolerability, and DLTs and to determine the MTD/RP2D of BMS-986249 administered as monotherapy and in combination with nivolumab in participants with advanced solid tumors (Parts 1A and 1B)

To evaluate the preliminary safety and tolerability of BMS-986249 in combination with nivolumab (Arm C and Arm F) relative to ipilimumab in combination with nivolumab (Arm D) in participants with previously untreated, unresectable or metastatic melanoma

To evaluate the preliminary efficacy of BMS- 986249 in combination with nivolumab (Arm C and Arm F) relative to historic nivolumab monotherapy data in participants with previously untreated, unresectable or metastatic melanoma

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

|                                                           |                  |
|-----------------------------------------------------------|------------------|
| Actual start date of recruitment                          | 06 December 2017 |
| Long term follow-up planned                               | No               |
| Independent data monitoring committee (IDMC) involvement? | No               |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                   |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Finland: 4        |
| Country: Number of subjects enrolled | Germany: 30       |
| Country: Number of subjects enrolled | Italy: 24         |
| Country: Number of subjects enrolled | Poland: 2         |
| Country: Number of subjects enrolled | Spain: 41         |
| Country: Number of subjects enrolled | Canada: 2         |
| Country: Number of subjects enrolled | United States: 90 |
| Country: Number of subjects enrolled | Argentina: 35     |
| Country: Number of subjects enrolled | Australia: 13     |
| Country: Number of subjects enrolled | Chile: 97         |
| Country: Number of subjects enrolled | Romania: 18       |
| Worldwide total number of subjects   | 356               |
| EEA total number of subjects         | 119               |

Notes:

| <b>Subjects enrolled per age group</b>    |     |
|-------------------------------------------|-----|
| In utero                                  | 0   |
| Preterm newborn - gestational age < 37 wk | 0   |
| Newborns (0-27 days)                      | 0   |
| Infants and toddlers (28 days-23 months)  | 0   |
| Children (2-11 years)                     | 0   |
| Adolescents (12-17 years)                 | 0   |
| Adults (18-64 years)                      | 221 |
| From 65 to 84 years                       | 135 |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

356 subjects enrolled and treated

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall Study (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Non-randomised - controlled    |
| Blinding used                | Not blinded                    |

### Arms

|                              |                                        |
|------------------------------|----------------------------------------|
| Are arms mutually exclusive? | Yes                                    |
| <b>Arm title</b>             | Part 1A: BMS-986249 240 mg Monotherapy |

Arm description:

BMS-986249 240 mg IV every 4 weeks (Q4W), up to 2 years

|                                        |                  |
|----------------------------------------|------------------|
| Arm type                               | Experimental     |
| Investigational medicinal product name | BMS-986249       |
| Investigational medicinal product code |                  |
| Other name                             |                  |
| Pharmaceutical forms                   | Injection        |
| Routes of administration               | Subcutaneous use |

Dosage and administration details:

160mg/vial (40mg/mL)

|                  |                                        |
|------------------|----------------------------------------|
| <b>Arm title</b> | Part 1A: BMS-986249 800 mg Monotherapy |
|------------------|----------------------------------------|

Arm description:

BMS-986249 800 mg IV every 4 weeks (Q4W), up to 2 years

|                                        |                  |
|----------------------------------------|------------------|
| Arm type                               | Experimental     |
| Investigational medicinal product name | BMS-986249       |
| Investigational medicinal product code |                  |
| Other name                             |                  |
| Pharmaceutical forms                   | Injection        |
| Routes of administration               | Subcutaneous use |

Dosage and administration details:

160mg/vial (40mg/mL)

|                  |                                         |
|------------------|-----------------------------------------|
| <b>Arm title</b> | Part 1A: BMS-986249 1600 mg Monotherapy |
|------------------|-----------------------------------------|

Arm description:

BMS-986249 1600 mg IV every 4 weeks (Q4W), up to 2 years

|                                        |                  |
|----------------------------------------|------------------|
| Arm type                               | Experimental     |
| Investigational medicinal product name | BMS-986249       |
| Investigational medicinal product code |                  |
| Other name                             |                  |
| Pharmaceutical forms                   | Injection        |
| Routes of administration               | Subcutaneous use |

Dosage and administration details:

160mg/vial (40mg/mL)

|                  |                                         |
|------------------|-----------------------------------------|
| <b>Arm title</b> | Part 1A: BMS-986249 2400 mg Monotherapy |
|------------------|-----------------------------------------|

|                                                                                   |                                                   |
|-----------------------------------------------------------------------------------|---------------------------------------------------|
| Arm description:                                                                  |                                                   |
| BMS-986249 2400 mg IV every 4 weeks (Q4W), up to 2 years                          |                                                   |
| Arm type                                                                          | Experimental                                      |
| Investigational medicinal product name                                            | BMS-986249                                        |
| Investigational medicinal product code                                            |                                                   |
| Other name                                                                        |                                                   |
| Pharmaceutical forms                                                              | Injection                                         |
| Routes of administration                                                          | Subcutaneous use                                  |
| Dosage and administration details:                                                |                                                   |
| 160mg/vial (40mg/mL)                                                              |                                                   |
| <b>Arm title</b>                                                                  | Part 1A: BMS-986249 1600 mg Q8W Monotherapy       |
| Arm description:                                                                  |                                                   |
| BMS-986249 1600 mg IV every 8 weeks (Q8W), up to 2 years                          |                                                   |
| Arm type                                                                          | Experimental                                      |
| Investigational medicinal product name                                            | BMS-986249                                        |
| Investigational medicinal product code                                            |                                                   |
| Other name                                                                        |                                                   |
| Pharmaceutical forms                                                              | Injection                                         |
| Routes of administration                                                          | Subcutaneous use                                  |
| Dosage and administration details:                                                |                                                   |
| 160mg/vial (40mg/mL)                                                              |                                                   |
| <b>Arm title</b>                                                                  | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination |
| Arm description:                                                                  |                                                   |
| BMS-986249 240 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years |                                                   |
| Arm type                                                                          | Experimental                                      |
| Investigational medicinal product name                                            | nivolumab                                         |
| Investigational medicinal product code                                            |                                                   |
| Other name                                                                        |                                                   |
| Pharmaceutical forms                                                              | Injection                                         |
| Routes of administration                                                          | Subcutaneous use                                  |
| Dosage and administration details:                                                |                                                   |
| 100mg/vial (10mg/mL)                                                              |                                                   |
| Investigational medicinal product name                                            | BMS-986249                                        |
| Investigational medicinal product code                                            |                                                   |
| Other name                                                                        |                                                   |
| Pharmaceutical forms                                                              | Injection                                         |
| Routes of administration                                                          | Subcutaneous use                                  |
| Dosage and administration details:                                                |                                                   |
| 160mg/vial (40mg/mL)                                                              |                                                   |
| <b>Arm title</b>                                                                  | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination  |
| Arm description:                                                                  |                                                   |
| BMS-986249 800 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years |                                                   |
| Arm type                                                                          | Experimental                                      |
| Investigational medicinal product name                                            | BMS-986249                                        |
| Investigational medicinal product code                                            |                                                   |
| Other name                                                                        |                                                   |
| Pharmaceutical forms                                                              | Injection                                         |
| Routes of administration                                                          | Subcutaneous use                                  |
| Dosage and administration details:                                                |                                                   |
| 160mg/vial (40mg/mL)                                                              |                                                   |

|                                                                                                    |                                                         |
|----------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| Investigational medicinal product name                                                             | nivolumab                                               |
| Investigational medicinal product code                                                             |                                                         |
| Other name                                                                                         |                                                         |
| Pharmaceutical forms                                                                               | Injection                                               |
| Routes of administration                                                                           | Subcutaneous use                                        |
| Dosage and administration details:                                                                 |                                                         |
| 100mg/vial (10mg/mL)                                                                               |                                                         |
| <b>Arm title</b>                                                                                   | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination |
| Arm description:                                                                                   |                                                         |
| BMS-986249 1200 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years                 |                                                         |
| Arm type                                                                                           | Experimental                                            |
| Investigational medicinal product name                                                             | nivolumab                                               |
| Investigational medicinal product code                                                             |                                                         |
| Other name                                                                                         |                                                         |
| Pharmaceutical forms                                                                               | Injection                                               |
| Routes of administration                                                                           | Subcutaneous use                                        |
| Dosage and administration details:                                                                 |                                                         |
| 100mg/vial (10mg/mL)                                                                               |                                                         |
| Investigational medicinal product name                                                             | BMS-986249                                              |
| Investigational medicinal product code                                                             |                                                         |
| Other name                                                                                         |                                                         |
| Pharmaceutical forms                                                                               | Injection                                               |
| Routes of administration                                                                           | Subcutaneous use                                        |
| Dosage and administration details:                                                                 |                                                         |
| 160mg/vial (40mg/mL)                                                                               |                                                         |
| <b>Arm title</b>                                                                                   | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination  |
| Arm description:                                                                                   |                                                         |
| BMS-986249 800 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years  |                                                         |
| Arm type                                                                                           | Experimental                                            |
| Investigational medicinal product name                                                             | BMS-986249                                              |
| Investigational medicinal product code                                                             |                                                         |
| Other name                                                                                         |                                                         |
| Pharmaceutical forms                                                                               | Injection                                               |
| Routes of administration                                                                           | Subcutaneous use                                        |
| Dosage and administration details:                                                                 |                                                         |
| 160mg/vial (40mg/mL)                                                                               |                                                         |
| Investigational medicinal product name                                                             | nivolumab                                               |
| Investigational medicinal product code                                                             |                                                         |
| Other name                                                                                         |                                                         |
| Pharmaceutical forms                                                                               | Injection                                               |
| Routes of administration                                                                           | Subcutaneous use                                        |
| Dosage and administration details:                                                                 |                                                         |
| 100mg/vial (10mg/mL)                                                                               |                                                         |
| <b>Arm title</b>                                                                                   | Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination       |
| Arm description:                                                                                   |                                                         |
| BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years |                                                         |
| Arm type                                                                                           | Experimental                                            |

|                                                                                                                                                                                              |                                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| Investigational medicinal product name                                                                                                                                                       | nivolumab                                              |
| Investigational medicinal product code                                                                                                                                                       |                                                        |
| Other name                                                                                                                                                                                   |                                                        |
| Pharmaceutical forms                                                                                                                                                                         | Injection                                              |
| Routes of administration                                                                                                                                                                     | Subcutaneous use                                       |
| Dosage and administration details:<br>100mg/vial (10mg/mL)                                                                                                                                   |                                                        |
| Investigational medicinal product name                                                                                                                                                       | BMS-986249                                             |
| Investigational medicinal product code                                                                                                                                                       |                                                        |
| Other name                                                                                                                                                                                   |                                                        |
| Pharmaceutical forms                                                                                                                                                                         | Injection                                              |
| Routes of administration                                                                                                                                                                     | Subcutaneous use                                       |
| Dosage and administration details:<br>160mg/vial (40mg/mL)                                                                                                                                   |                                                        |
| <b>Arm title</b>                                                                                                                                                                             | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination |
| Arm description:<br>BMS-986249 1600 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                                       |                                                        |
| Arm type                                                                                                                                                                                     | Experimental                                           |
| Investigational medicinal product name                                                                                                                                                       | nivolumab                                              |
| Investigational medicinal product code                                                                                                                                                       |                                                        |
| Other name                                                                                                                                                                                   |                                                        |
| Pharmaceutical forms                                                                                                                                                                         | Injection                                              |
| Routes of administration                                                                                                                                                                     | Subcutaneous use                                       |
| Dosage and administration details:<br>100mg/vial (10mg/mL)                                                                                                                                   |                                                        |
| Investigational medicinal product name                                                                                                                                                       | BMS-986249                                             |
| Investigational medicinal product code                                                                                                                                                       |                                                        |
| Other name                                                                                                                                                                                   |                                                        |
| Pharmaceutical forms                                                                                                                                                                         | Injection                                              |
| Routes of administration                                                                                                                                                                     | Subcutaneous use                                       |
| Dosage and administration details:<br>160mg/vial (40mg/mL)                                                                                                                                   |                                                        |
| <b>Arm title</b>                                                                                                                                                                             | Part 2A Arm A: BMS-986249 240 mg Q3W + Nivo 360 mg Q3W |
| Arm description:<br>BMS-986249 240 mg IV every 3 weeks (Q3W) + nivolumab 360 mg IV every 3 weeks (Q3W) (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W) (maintenance), up to 2 years. |                                                        |
| Arm type                                                                                                                                                                                     | Experimental                                           |
| Investigational medicinal product name                                                                                                                                                       | nivolumab                                              |
| Investigational medicinal product code                                                                                                                                                       |                                                        |
| Other name                                                                                                                                                                                   |                                                        |
| Pharmaceutical forms                                                                                                                                                                         | Injection                                              |
| Routes of administration                                                                                                                                                                     | Subcutaneous use                                       |
| Dosage and administration details:<br>100mg/vial (10mg/mL)                                                                                                                                   |                                                        |
| Investigational medicinal product name                                                                                                                                                       | BMS-986249                                             |
| Investigational medicinal product code                                                                                                                                                       |                                                        |
| Other name                                                                                                                                                                                   |                                                        |
| Pharmaceutical forms                                                                                                                                                                         | Injection                                              |
| Routes of administration                                                                                                                                                                     | Subcutaneous use                                       |
| Dosage and administration details:<br>160mg/vial (40mg/mL)                                                                                                                                   |                                                        |

|                                                                                                                                                                              |                                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| <b>Arm title</b>                                                                                                                                                             | Part 2A Arm B: BMS-986249 800 mg + Nivo 480 mg Q4W       |
| Arm description:<br>BMS-986249 800 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                        |                                                          |
| Arm type                                                                                                                                                                     | Experimental                                             |
| Investigational medicinal product name                                                                                                                                       | nivolumab                                                |
| Investigational medicinal product code                                                                                                                                       |                                                          |
| Other name                                                                                                                                                                   |                                                          |
| Pharmaceutical forms                                                                                                                                                         | Injection                                                |
| Routes of administration                                                                                                                                                     | Subcutaneous use                                         |
| Dosage and administration details:<br>100mg/vial (10mg/mL)                                                                                                                   |                                                          |
| Investigational medicinal product name                                                                                                                                       | BMS-986249                                               |
| Investigational medicinal product code                                                                                                                                       |                                                          |
| Other name                                                                                                                                                                   |                                                          |
| Pharmaceutical forms                                                                                                                                                         | Injection                                                |
| Routes of administration                                                                                                                                                     | Subcutaneous use                                         |
| Dosage and administration details:<br>160mg/vial (40mg/mL)                                                                                                                   |                                                          |
| <b>Arm title</b>                                                                                                                                                             | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W  |
| Arm description:<br>BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                       |                                                          |
| Arm type                                                                                                                                                                     | Experimental                                             |
| Investigational medicinal product name                                                                                                                                       | nivolumab                                                |
| Investigational medicinal product code                                                                                                                                       |                                                          |
| Other name                                                                                                                                                                   |                                                          |
| Pharmaceutical forms                                                                                                                                                         | Injection                                                |
| Routes of administration                                                                                                                                                     | Subcutaneous use                                         |
| Dosage and administration details:<br>100mg/vial (10mg/mL)                                                                                                                   |                                                          |
| Investigational medicinal product name                                                                                                                                       | BMS-986249                                               |
| Investigational medicinal product code                                                                                                                                       |                                                          |
| Other name                                                                                                                                                                   |                                                          |
| Pharmaceutical forms                                                                                                                                                         | Injection                                                |
| Routes of administration                                                                                                                                                     | Subcutaneous use                                         |
| Dosage and administration details:<br>160mg/vial (40mg/mL)                                                                                                                   |                                                          |
| <b>Arm title</b>                                                                                                                                                             | Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W |
| Arm description:<br>Ipilimumab 3 mg/kg IV every 3 weeks (Q3W) + nivolumab 1 mg/kg IV Q3W (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W) monotherapy, up to 2 years. |                                                          |
| Arm type                                                                                                                                                                     | Experimental                                             |
| Investigational medicinal product name                                                                                                                                       | ipilimumab                                               |
| Investigational medicinal product code                                                                                                                                       |                                                          |
| Other name                                                                                                                                                                   |                                                          |
| Pharmaceutical forms                                                                                                                                                         | Injection                                                |
| Routes of administration                                                                                                                                                     | Subcutaneous use                                         |
| Dosage and administration details:<br>50mg/vial (5mg/mL)                                                                                                                     |                                                          |

|                                                                                                                        |                                                        |
|------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| Investigational medicinal product name                                                                                 | nivolumab                                              |
| Investigational medicinal product code                                                                                 |                                                        |
| Other name                                                                                                             |                                                        |
| Pharmaceutical forms                                                                                                   | Injection                                              |
| Routes of administration                                                                                               | Subcutaneous use                                       |
| Dosage and administration details:<br>100mg/vial (10mg/mL)                                                             |                                                        |
| <b>Arm title</b>                                                                                                       | Part 2A Arm E: Nivo 480 mg Q4W Monotherapy             |
| Arm description:<br>Nivolumab 480 mg IV every 4 weeks (Q4W) monotherapy, up to 2 years.                                |                                                        |
| Arm type                                                                                                               | Experimental                                           |
| Investigational medicinal product name                                                                                 | nivolumab                                              |
| Investigational medicinal product code                                                                                 |                                                        |
| Other name                                                                                                             |                                                        |
| Pharmaceutical forms                                                                                                   | Injection                                              |
| Routes of administration                                                                                               | Subcutaneous use                                       |
| Dosage and administration details:<br>100mg/vial (10mg/mL)                                                             |                                                        |
| <b>Arm title</b>                                                                                                       | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W |
| Arm description:<br>BMS-986249 600 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years.                 |                                                        |
| Arm type                                                                                                               | Experimental                                           |
| Investigational medicinal product name                                                                                 | nivolumab                                              |
| Investigational medicinal product code                                                                                 |                                                        |
| Other name                                                                                                             |                                                        |
| Pharmaceutical forms                                                                                                   | Injection                                              |
| Routes of administration                                                                                               | Subcutaneous use                                       |
| Dosage and administration details:<br>100mg/vial (10mg/mL)                                                             |                                                        |
| Investigational medicinal product name                                                                                 | BMS-986249                                             |
| Investigational medicinal product code                                                                                 |                                                        |
| Other name                                                                                                             |                                                        |
| Pharmaceutical forms                                                                                                   | Injection                                              |
| Routes of administration                                                                                               | Subcutaneous use                                       |
| Dosage and administration details:<br>160mg/vial (40mg/mL)                                                             |                                                        |
| <b>Arm title</b>                                                                                                       | Part 2B: Cohort 1 (Advanced or Intermediate HCC)       |
| Arm description:<br>BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years |                                                        |
| Arm type                                                                                                               | Experimental                                           |
| Investigational medicinal product name                                                                                 | nivolumab                                              |
| Investigational medicinal product code                                                                                 |                                                        |
| Other name                                                                                                             |                                                        |
| Pharmaceutical forms                                                                                                   | Injection                                              |
| Routes of administration                                                                                               | Subcutaneous use                                       |
| Dosage and administration details:<br>100mg/vial (10mg/mL)                                                             |                                                        |
| Investigational medicinal product name                                                                                 | BMS-986249                                             |
| Investigational medicinal product code                                                                                 |                                                        |
| Other name                                                                                                             |                                                        |

|                                    |                  |
|------------------------------------|------------------|
| Pharmaceutical forms               | Injection        |
| Routes of administration           | Subcutaneous use |
| Dosage and administration details: |                  |
| 160mg/vial (40mg/mL)               |                  |

|                  |                                     |
|------------------|-------------------------------------|
| <b>Arm title</b> | Part 2B: Cohort 2 (Metastatic CRPC) |
|------------------|-------------------------------------|

Arm description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

|                                        |                  |
|----------------------------------------|------------------|
| Arm type                               | Experimental     |
| Investigational medicinal product name | nivolumab        |
| Investigational medicinal product code |                  |
| Other name                             |                  |
| Pharmaceutical forms                   | Injection        |
| Routes of administration               | Subcutaneous use |

Dosage and administration details:

100mg/vial (10mg/mL)

|                                        |                  |
|----------------------------------------|------------------|
| Investigational medicinal product name | BMS-986249       |
| Investigational medicinal product code |                  |
| Other name                             |                  |
| Pharmaceutical forms                   | Injection        |
| Routes of administration               | Subcutaneous use |

Dosage and administration details:

160mg/vial (40mg/mL)

|                  |                                       |
|------------------|---------------------------------------|
| <b>Arm title</b> | Part 2B: Cohort 3 (Unresectable TNBC) |
|------------------|---------------------------------------|

Arm description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

|                                        |                  |
|----------------------------------------|------------------|
| Arm type                               | Experimental     |
| Investigational medicinal product name | nivolumab        |
| Investigational medicinal product code |                  |
| Other name                             |                  |
| Pharmaceutical forms                   | Injection        |
| Routes of administration               | Subcutaneous use |

Dosage and administration details:

100mg/vial (10mg/mL)

|                                        |                  |
|----------------------------------------|------------------|
| Investigational medicinal product name | BMS-986249       |
| Investigational medicinal product code |                  |
| Other name                             |                  |
| Pharmaceutical forms                   | Injection        |
| Routes of administration               | Subcutaneous use |

Dosage and administration details:

160mg/vial (40mg/mL)

| Number of subjects in period 1                     | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy |
|----------------------------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|
| Started                                            | 6                                      | 11                                     | 10                                      |
| Treated                                            | 6                                      | 11                                     | 10                                      |
| Completed                                          | 0                                      | 0                                      | 0                                       |
| Not completed                                      | 6                                      | 11                                     | 10                                      |
| Adverse event, serious fatal                       | -                                      | -                                      | -                                       |
| Disease progression                                | 6                                      | 8                                      | 5                                       |
| Participant withdrew consent                       | -                                      | 1                                      | 1                                       |
| Study drug toxicity                                | -                                      | 1                                      | 4                                       |
| Randomized but not treated                         | -                                      | -                                      | -                                       |
| Participant no longer meets study criteria         | -                                      | -                                      | -                                       |
| Adverse event unrelated to study drug              | -                                      | -                                      | -                                       |
| Other reasons                                      | -                                      | -                                      | -                                       |
| Lost to follow-up                                  | -                                      | -                                      | -                                       |
| Participant request to discontinue study treatment | -                                      | 1                                      | -                                       |

| Number of subjects in period 1                     | Part 1A: BMS-986249 2400 mg Monotherapy | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination |
|----------------------------------------------------|-----------------------------------------|---------------------------------------------|---------------------------------------------------|
| Started                                            | 1                                       | 11                                          | 12                                                |
| Treated                                            | 1                                       | 11                                          | 12                                                |
| Completed                                          | 0                                       | 0                                           | 0                                                 |
| Not completed                                      | 1                                       | 11                                          | 12                                                |
| Adverse event, serious fatal                       | -                                       | -                                           | -                                                 |
| Disease progression                                | 1                                       | 9                                           | 9                                                 |
| Participant withdrew consent                       | -                                       | -                                           | -                                                 |
| Study drug toxicity                                | -                                       | 1                                           | 2                                                 |
| Randomized but not treated                         | -                                       | -                                           | -                                                 |
| Participant no longer meets study criteria         | -                                       | -                                           | -                                                 |
| Adverse event unrelated to study drug              | -                                       | -                                           | -                                                 |
| Other reasons                                      | -                                       | -                                           | -                                                 |
| Lost to follow-up                                  | -                                       | -                                           | -                                                 |
| Participant request to discontinue study treatment | -                                       | 1                                           | 1                                                 |

| Number of subjects in period 1 | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination |
|--------------------------------|--------------------------------------------------|---------------------------------------------------------|--------------------------------------------------------|
| Started                        | 11                                               | 9                                                       | 13                                                     |
| Treated                        | 11                                               | 9                                                       | 13                                                     |

|                                                    |    |   |    |
|----------------------------------------------------|----|---|----|
| Completed                                          | 0  | 0 | 0  |
| Not completed                                      | 11 | 9 | 13 |
| Adverse event, serious fatal                       | -  | - | -  |
| Disease progression                                | 4  | 6 | 10 |
| Participant withdrew consent                       | 1  | 1 | 1  |
| Study drug toxicity                                | 4  | 2 | 2  |
| Randomized but not treated                         | -  | - | -  |
| Participant no longer meets study criteria         | -  | - | -  |
| Adverse event unrelated to study drug              | 1  | - | -  |
| Other reasons                                      | -  | - | -  |
| Lost to follow-up                                  | -  | - | -  |
| Participant request to discontinue study treatment | 1  | - | -  |

| <b>Number of subjects in period 1</b>              | Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination | Part 2A Arm A: BMS-986249 240 mg Q3W + Nivo 360 mg Q3W |
|----------------------------------------------------|---------------------------------------------------|--------------------------------------------------------|--------------------------------------------------------|
| Started                                            | 9                                                 | 10                                                     | 3                                                      |
| Treated                                            | 9                                                 | 10                                                     | 3                                                      |
| Completed                                          | 1                                                 | 0                                                      | 0                                                      |
| Not completed                                      | 8                                                 | 10                                                     | 3                                                      |
| Adverse event, serious fatal                       | -                                                 | -                                                      | -                                                      |
| Disease progression                                | 7                                                 | 4                                                      | 1                                                      |
| Participant withdrew consent                       | -                                                 | -                                                      | 1                                                      |
| Study drug toxicity                                | -                                                 | 6                                                      | 1                                                      |
| Randomized but not treated                         | -                                                 | -                                                      | -                                                      |
| Participant no longer meets study criteria         | -                                                 | -                                                      | -                                                      |
| Adverse event unrelated to study drug              | 1                                                 | -                                                      | -                                                      |
| Other reasons                                      | -                                                 | -                                                      | -                                                      |
| Lost to follow-up                                  | -                                                 | -                                                      | -                                                      |
| Participant request to discontinue study treatment | -                                                 | -                                                      | -                                                      |

| <b>Number of subjects in period 1</b> | Part 2A Arm B: BMS-986249 800 mg + Nivo 480 mg Q4W | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W | Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W |
|---------------------------------------|----------------------------------------------------|---------------------------------------------------------|----------------------------------------------------------|
| Started                               | 3                                                  | 58                                                      | 59                                                       |
| Treated                               | 3                                                  | 57                                                      | 58                                                       |
| Completed                             | 0                                                  | 6                                                       | 7                                                        |
| Not completed                         | 3                                                  | 52                                                      | 52                                                       |
| Adverse event, serious fatal          | -                                                  | 1                                                       | -                                                        |
| Disease progression                   | 1                                                  | 25                                                      | 22                                                       |
| Participant withdrew consent          | -                                                  | -                                                       | 3                                                        |

|                                                    |   |    |    |
|----------------------------------------------------|---|----|----|
| Study drug toxicity                                | 2 | 19 | 19 |
| Randomized but not treated                         | - | 1  | 1  |
| Participant no longer meets study criteria         | - | -  | 2  |
| Adverse event unrelated to study drug              | - | 4  | 2  |
| Other reasons                                      | - | 1  | 2  |
| Lost to follow-up                                  | - | -  | -  |
| Participant request to discontinue study treatment | - | 1  | 1  |

| Number of subjects in period 1                     | Part 2A Arm E: Nivo 480 mg Q4W Monotherapy | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W | Part 2B: Cohort 1 (Advanced or Intermediate HCC) |
|----------------------------------------------------|--------------------------------------------|--------------------------------------------------------|--------------------------------------------------|
|                                                    |                                            |                                                        |                                                  |
| Started                                            | 3                                          | 36                                                     | 5                                                |
| Treated                                            | 3                                          | 36                                                     | 5                                                |
| Completed                                          | 1                                          | 2                                                      | 0                                                |
| Not completed                                      | 2                                          | 34                                                     | 5                                                |
| Adverse event, serious fatal                       | -                                          | -                                                      | -                                                |
| Disease progression                                | 2                                          | 10                                                     | 1                                                |
| Participant withdrew consent                       | -                                          | 1                                                      | -                                                |
| Study drug toxicity                                | -                                          | 18                                                     | 3                                                |
| Randomized but not treated                         | -                                          | -                                                      | -                                                |
| Participant no longer meets study criteria         | -                                          | 2                                                      | -                                                |
| Adverse event unrelated to study drug              | -                                          | 2                                                      | 1                                                |
| Other reasons                                      | -                                          | 1                                                      | -                                                |
| Lost to follow-up                                  | -                                          | -                                                      | -                                                |
| Participant request to discontinue study treatment | -                                          | -                                                      | -                                                |

| Number of subjects in period 1             | Part 2B: Cohort 2 (Metastatic CRPC) | Part 2B: Cohort 3 (Unresectable TNBC) |
|--------------------------------------------|-------------------------------------|---------------------------------------|
| Started                                    | 41                                  | 45                                    |
| Treated                                    | 41                                  | 45                                    |
| Completed                                  | 1                                   | 3                                     |
| Not completed                              | 40                                  | 42                                    |
| Adverse event, serious fatal               | 1                                   | -                                     |
| Disease progression                        | 18                                  | 28                                    |
| Participant withdrew consent               | 4                                   | 2                                     |
| Study drug toxicity                        | 11                                  | 7                                     |
| Randomized but not treated                 | -                                   | -                                     |
| Participant no longer meets study criteria | -                                   | -                                     |
| Adverse event unrelated to study drug      | 3                                   | 2                                     |
| Other reasons                              | -                                   | 2                                     |

|                                                    |   |   |
|----------------------------------------------------|---|---|
| Lost to follow-up                                  | 2 | 1 |
| Participant request to discontinue study treatment | 1 | - |

## Baseline characteristics

| Reporting groups                                                                                                                                                                                         |                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| Reporting group title                                                                                                                                                                                    | Part 1A: BMS-986249 240 mg Monotherapy                   |
| Reporting group description:<br>BMS-986249 240 mg IV every 4 weeks (Q4W), up to 2 years                                                                                                                  |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1A: BMS-986249 800 mg Monotherapy                   |
| Reporting group description:<br>BMS-986249 800 mg IV every 4 weeks (Q4W), up to 2 years                                                                                                                  |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1A: BMS-986249 1600 mg Monotherapy                  |
| Reporting group description:<br>BMS-986249 1600 mg IV every 4 weeks (Q4W), up to 2 years                                                                                                                 |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1A: BMS-986249 2400 mg Monotherapy                  |
| Reporting group description:<br>BMS-986249 2400 mg IV every 4 weeks (Q4W), up to 2 years                                                                                                                 |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1A: BMS-986249 1600 mg Q8W Monotherapy              |
| Reporting group description:<br>BMS-986249 1600 mg IV every 8 weeks (Q8W), up to 2 years                                                                                                                 |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination        |
| Reporting group description:<br>BMS-986249 240 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years                                                                                        |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination         |
| Reporting group description:<br>BMS-986249 800 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years                                                                                        |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination  |
| Reporting group description:<br>BMS-986249 1200 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years                                                                                       |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination   |
| Reporting group description:<br>BMS-986249 800 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                                        |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination        |
| Reporting group description:<br>BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                                       |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination   |
| Reporting group description:<br>BMS-986249 1600 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                                       |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 2A Arm A: BMS-986249 240 mg Q3W + Nivo 360 mg Q3W   |
| Reporting group description:<br>BMS-986249 240 mg IV every 3 weeks (Q3W) + nivolumab 360 mg IV every 3 weeks (Q3W) (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W) (maintenance), up to 2 years. |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 2A Arm B: BMS-986249 800 mg + Nivo 480 mg Q4W       |
| Reporting group description:<br>BMS-986249 800 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                                        |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W  |
| Reporting group description:<br>BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                                       |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W |

Reporting group description:

Ipilimumab 3 mg/kg IV every 3 weeks (Q3W) + nivolumab 1 mg/kg IV Q3W (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W) monotherapy, up to 2 years.

|                       |                                            |
|-----------------------|--------------------------------------------|
| Reporting group title | Part 2A Arm E: Nivo 480 mg Q4W Monotherapy |
|-----------------------|--------------------------------------------|

Reporting group description:

Nivolumab 480 mg IV every 4 weeks (Q4W) monotherapy, up to 2 years.

|                       |                                                        |
|-----------------------|--------------------------------------------------------|
| Reporting group title | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W |
|-----------------------|--------------------------------------------------------|

Reporting group description:

BMS-986249 600 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years.

|                       |                                                  |
|-----------------------|--------------------------------------------------|
| Reporting group title | Part 2B: Cohort 1 (Advanced or Intermediate HCC) |
|-----------------------|--------------------------------------------------|

Reporting group description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years

|                       |                                     |
|-----------------------|-------------------------------------|
| Reporting group title | Part 2B: Cohort 2 (Metastatic CRPC) |
|-----------------------|-------------------------------------|

Reporting group description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

|                       |                                       |
|-----------------------|---------------------------------------|
| Reporting group title | Part 2B: Cohort 3 (Unresectable TNBC) |
|-----------------------|---------------------------------------|

Reporting group description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

| Reporting group values                    | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy |
|-------------------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|
| Number of subjects                        | 6                                      | 11                                     | 10                                      |
| Age categorical                           |                                        |                                        |                                         |
| Units: Subjects                           |                                        |                                        |                                         |
| Adults (18-64 years)                      | 4                                      | 6                                      | 5                                       |
| From 65-84 years                          | 2                                      | 5                                      | 5                                       |
| Age Continuous                            |                                        |                                        |                                         |
| Here "99999" = NA                         |                                        |                                        |                                         |
| Units: years                              |                                        |                                        |                                         |
| arithmetic mean                           | 54.0                                   | 64.8                                   | 60.4                                    |
| standard deviation                        | ± 18.9                                 | ± 7.5                                  | ± 10.2                                  |
| Sex: Female, Male                         |                                        |                                        |                                         |
| Units: Participants                       |                                        |                                        |                                         |
| Female                                    | 3                                      | 8                                      | 8                                       |
| Male                                      | 3                                      | 3                                      | 2                                       |
| Race (NIH/OMB)                            |                                        |                                        |                                         |
| Units: Subjects                           |                                        |                                        |                                         |
| American Indian or Alaska Native          | 0                                      | 0                                      | 0                                       |
| Asian                                     | 0                                      | 0                                      | 1                                       |
| Native Hawaiian or Other Pacific Islander | 0                                      | 0                                      | 0                                       |
| Black or African American                 | 1                                      | 0                                      | 1                                       |
| White                                     | 4                                      | 11                                     | 7                                       |
| More than one race                        | 0                                      | 0                                      | 0                                       |
| Unknown or Not Reported                   | 1                                      | 0                                      | 1                                       |
| Ethnicity (NIH/OMB)                       |                                        |                                        |                                         |
| Units: Subjects                           |                                        |                                        |                                         |
| Hispanic or Latino                        | 1                                      | 1                                      | 0                                       |

|                         |   |    |   |
|-------------------------|---|----|---|
| Not Hispanic or Latino  | 5 | 10 | 8 |
| Unknown or Not Reported | 0 | 0  | 2 |

| Reporting group values                    | Part 1A: BMS-986249 2400 mg Monotherapy | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination |
|-------------------------------------------|-----------------------------------------|---------------------------------------------|---------------------------------------------------|
| Number of subjects                        | 1                                       | 11                                          | 12                                                |
| Age categorical<br>Units: Subjects        |                                         |                                             |                                                   |
| Adults (18-64 years)                      | 1                                       | 6                                           | 10                                                |
| From 65-84 years                          | 0                                       | 5                                           | 2                                                 |
| Age Continuous                            |                                         |                                             |                                                   |
| Here "99999" = NA                         |                                         |                                             |                                                   |
| Units: years                              |                                         |                                             |                                                   |
| arithmetic mean                           | 64                                      | 60.3                                        | 56.3                                              |
| standard deviation                        | ± 99999                                 | ± 11.6                                      | ± 8.8                                             |
| Sex: Female, Male<br>Units: Participants  |                                         |                                             |                                                   |
| Female                                    | 0                                       | 7                                           | 9                                                 |
| Male                                      | 1                                       | 4                                           | 3                                                 |
| Race (NIH/OMB)<br>Units: Subjects         |                                         |                                             |                                                   |
| American Indian or Alaska Native          | 0                                       | 0                                           | 0                                                 |
| Asian                                     | 0                                       | 0                                           | 0                                                 |
| Native Hawaiian or Other Pacific Islander | 0                                       | 0                                           | 0                                                 |
| Black or African American                 | 0                                       | 2                                           | 0                                                 |
| White                                     | 1                                       | 8                                           | 11                                                |
| More than one race                        | 0                                       | 0                                           | 0                                                 |
| Unknown or Not Reported                   | 0                                       | 1                                           | 1                                                 |
| Ethnicity (NIH/OMB)<br>Units: Subjects    |                                         |                                             |                                                   |
| Hispanic or Latino                        | 1                                       | 2                                           | 2                                                 |
| Not Hispanic or Latino                    | 0                                       | 7                                           | 10                                                |
| Unknown or Not Reported                   | 0                                       | 2                                           | 0                                                 |

| Reporting group values             | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination |
|------------------------------------|--------------------------------------------------|---------------------------------------------------------|--------------------------------------------------------|
| Number of subjects                 | 11                                               | 9                                                       | 13                                                     |
| Age categorical<br>Units: Subjects |                                                  |                                                         |                                                        |
| Adults (18-64 years)               | 10                                               | 5                                                       | 11                                                     |
| From 65-84 years                   | 1                                                | 4                                                       | 2                                                      |
| Age Continuous                     |                                                  |                                                         |                                                        |
| Here "99999" = NA                  |                                                  |                                                         |                                                        |
| Units: years                       |                                                  |                                                         |                                                        |
| arithmetic mean                    | 53.9                                             | 61.4                                                    | 55.3                                                   |
| standard deviation                 | ± 12.4                                           | ± 11.2                                                  | ± 11.4                                                 |

|                                           |    |   |    |
|-------------------------------------------|----|---|----|
| Sex: Female, Male<br>Units: Participants  |    |   |    |
| Female                                    | 4  | 1 | 4  |
| Male                                      | 7  | 8 | 9  |
| Race (NIH/OMB)<br>Units: Subjects         |    |   |    |
| American Indian or Alaska Native          | 0  | 0 | 0  |
| Asian                                     | 0  | 0 | 2  |
| Native Hawaiian or Other Pacific Islander | 0  | 0 | 0  |
| Black or African American                 | 0  | 1 | 2  |
| White                                     | 11 | 6 | 9  |
| More than one race                        | 0  | 0 | 0  |
| Unknown or Not Reported                   | 0  | 2 | 0  |
| Ethnicity (NIH/OMB)<br>Units: Subjects    |    |   |    |
| Hispanic or Latino                        | 1  | 0 | 1  |
| Not Hispanic or Latino                    | 10 | 6 | 10 |
| Unknown or Not Reported                   | 0  | 3 | 2  |

| <b>Reporting group values</b>                         | Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination | Part 2A Arm A: BMS-986249 240 mg Q3W + Nivo 360 mg Q3W |
|-------------------------------------------------------|---------------------------------------------------|--------------------------------------------------------|--------------------------------------------------------|
| Number of subjects                                    | 9                                                 | 10                                                     | 3                                                      |
| Age categorical<br>Units: Subjects                    |                                                   |                                                        |                                                        |
| Adults (18-64 years)                                  | 7                                                 | 6                                                      | 1                                                      |
| From 65-84 years                                      | 2                                                 | 4                                                      | 2                                                      |
| Age Continuous                                        |                                                   |                                                        |                                                        |
| Here "99999" = NA                                     |                                                   |                                                        |                                                        |
| Units: years<br>arithmetic mean<br>standard deviation | 59.0<br>± 8.0                                     | 60.1<br>± 9.9                                          | 60.7<br>± 13.6                                         |
| Sex: Female, Male<br>Units: Participants              |                                                   |                                                        |                                                        |
| Female                                                | 5                                                 | 4                                                      | 1                                                      |
| Male                                                  | 4                                                 | 6                                                      | 2                                                      |
| Race (NIH/OMB)<br>Units: Subjects                     |                                                   |                                                        |                                                        |
| American Indian or Alaska Native                      | 0                                                 | 0                                                      | 0                                                      |
| Asian                                                 | 0                                                 | 0                                                      | 0                                                      |
| Native Hawaiian or Other Pacific Islander             | 0                                                 | 0                                                      | 0                                                      |
| Black or African American                             | 0                                                 | 0                                                      | 0                                                      |
| White                                                 | 9                                                 | 10                                                     | 3                                                      |
| More than one race                                    | 0                                                 | 0                                                      | 0                                                      |
| Unknown or Not Reported                               | 0                                                 | 0                                                      | 0                                                      |
| Ethnicity (NIH/OMB)<br>Units: Subjects                |                                                   |                                                        |                                                        |
| Hispanic or Latino                                    | 0                                                 | 2                                                      | 0                                                      |
| Not Hispanic or Latino                                | 8                                                 | 6                                                      | 3                                                      |
| Unknown or Not Reported                               | 1                                                 | 2                                                      | 0                                                      |

| Reporting group values                    | Part 2A Arm B:<br>BMS-986249 800 mg + Nivo 480 mg Q4W | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W | Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W |
|-------------------------------------------|-------------------------------------------------------|---------------------------------------------------------|----------------------------------------------------------|
| Number of subjects                        | 3                                                     | 58                                                      | 59                                                       |
| Age categorical<br>Units: Subjects        |                                                       |                                                         |                                                          |
| Adults (18-64 years)                      | 0                                                     | 34                                                      | 39                                                       |
| From 65-84 years                          | 3                                                     | 24                                                      | 20                                                       |
| Age Continuous                            |                                                       |                                                         |                                                          |
| Here "99999" = NA                         |                                                       |                                                         |                                                          |
| Units: years                              |                                                       |                                                         |                                                          |
| arithmetic mean                           | 73.3                                                  | 61.4                                                    | 57.3                                                     |
| standard deviation                        | ± 7.6                                                 | ± 14.7                                                  | ± 13.8                                                   |
| Sex: Female, Male<br>Units: Participants  |                                                       |                                                         |                                                          |
| Female                                    | 1                                                     | 22                                                      | 27                                                       |
| Male                                      | 2                                                     | 36                                                      | 32                                                       |
| Race (NIH/OMB)<br>Units: Subjects         |                                                       |                                                         |                                                          |
| American Indian or Alaska Native          | 0                                                     | 0                                                       | 0                                                        |
| Asian                                     | 0                                                     | 0                                                       | 2                                                        |
| Native Hawaiian or Other Pacific Islander | 0                                                     | 0                                                       | 0                                                        |
| Black or African American                 | 0                                                     | 1                                                       | 0                                                        |
| White                                     | 3                                                     | 57                                                      | 57                                                       |
| More than one race                        | 0                                                     | 0                                                       | 0                                                        |
| Unknown or Not Reported                   | 0                                                     | 0                                                       | 0                                                        |
| Ethnicity (NIH/OMB)<br>Units: Subjects    |                                                       |                                                         |                                                          |
| Hispanic or Latino                        | 1                                                     | 7                                                       | 11                                                       |
| Not Hispanic or Latino                    | 1                                                     | 11                                                      | 8                                                        |
| Unknown or Not Reported                   | 1                                                     | 40                                                      | 40                                                       |

| Reporting group values                   | Part 2A Arm E: Nivo 480 mg Q4W Monotherapy | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W | Part 2B: Cohort 1 (Advanced or Intermediate HCC) |
|------------------------------------------|--------------------------------------------|--------------------------------------------------------|--------------------------------------------------|
| Number of subjects                       | 3                                          | 36                                                     | 5                                                |
| Age categorical<br>Units: Subjects       |                                            |                                                        |                                                  |
| Adults (18-64 years)                     | 1                                          | 22                                                     | 3                                                |
| From 65-84 years                         | 2                                          | 14                                                     | 2                                                |
| Age Continuous                           |                                            |                                                        |                                                  |
| Here "99999" = NA                        |                                            |                                                        |                                                  |
| Units: years                             |                                            |                                                        |                                                  |
| arithmetic mean                          | 59.7                                       | 60.3                                                   | 60.4                                             |
| standard deviation                       | ± 24.8                                     | ± 12.4                                                 | ± 9.8                                            |
| Sex: Female, Male<br>Units: Participants |                                            |                                                        |                                                  |
| Female                                   | 1                                          | 19                                                     | 1                                                |
| Male                                     | 2                                          | 17                                                     | 4                                                |

|                                           |   |    |   |
|-------------------------------------------|---|----|---|
| Race (NIH/OMB)                            |   |    |   |
| Units: Subjects                           |   |    |   |
| American Indian or Alaska Native          | 0 | 0  | 0 |
| Asian                                     | 0 | 0  | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0  | 0 |
| Black or African American                 | 0 | 0  | 0 |
| White                                     | 3 | 36 | 5 |
| More than one race                        | 0 | 0  | 0 |
| Unknown or Not Reported                   | 0 | 0  | 0 |
| Ethnicity (NIH/OMB)                       |   |    |   |
| Units: Subjects                           |   |    |   |
| Hispanic or Latino                        | 0 | 2  | 1 |
| Not Hispanic or Latino                    | 1 | 11 | 1 |
| Unknown or Not Reported                   | 2 | 23 | 3 |

| Reporting group values                    | Part 2B: Cohort 2<br>(Metastatic CRPC) | Part 2B: Cohort 3<br>(Unresectable TNBC) | Total |
|-------------------------------------------|----------------------------------------|------------------------------------------|-------|
| Number of subjects                        | 41                                     | 45                                       | 356   |
| Age categorical                           |                                        |                                          |       |
| Units: Subjects                           |                                        |                                          |       |
| Adults (18-64 years)                      | 12                                     | 38                                       | 221   |
| From 65-84 years                          | 29                                     | 7                                        | 135   |
| Age Continuous                            |                                        |                                          |       |
| Here "99999" = NA                         |                                        |                                          |       |
| Units: years                              |                                        |                                          |       |
| arithmetic mean                           | 68.6                                   | 51.2                                     |       |
| standard deviation                        | ± 8.0                                  | ± 12.8                                   | -     |
| Sex: Female, Male                         |                                        |                                          |       |
| Units: Participants                       |                                        |                                          |       |
| Female                                    | 0                                      | 45                                       | 170   |
| Male                                      | 41                                     | 0                                        | 186   |
| Race (NIH/OMB)                            |                                        |                                          |       |
| Units: Subjects                           |                                        |                                          |       |
| American Indian or Alaska Native          | 0                                      | 0                                        | 0     |
| Asian                                     | 0                                      | 0                                        | 5     |
| Native Hawaiian or Other Pacific Islander | 0                                      | 0                                        | 0     |
| Black or African American                 | 0                                      | 1                                        | 9     |
| White                                     | 40                                     | 44                                       | 335   |
| More than one race                        | 0                                      | 0                                        | 0     |
| Unknown or Not Reported                   | 1                                      | 0                                        | 7     |
| Ethnicity (NIH/OMB)                       |                                        |                                          |       |
| Units: Subjects                           |                                        |                                          |       |
| Hispanic or Latino                        | 3                                      | 3                                        | 39    |
| Not Hispanic or Latino                    | 6                                      | 13                                       | 135   |
| Unknown or Not Reported                   | 32                                     | 29                                       | 182   |

## End points

### End points reporting groups

|                                                                                                                                                                                                          |                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| Reporting group title                                                                                                                                                                                    | Part 1A: BMS-986249 240 mg Monotherapy                   |
| Reporting group description:<br>BMS-986249 240 mg IV every 4 weeks (Q4W), up to 2 years                                                                                                                  |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1A: BMS-986249 800 mg Monotherapy                   |
| Reporting group description:<br>BMS-986249 800 mg IV every 4 weeks (Q4W), up to 2 years                                                                                                                  |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1A: BMS-986249 1600 mg Monotherapy                  |
| Reporting group description:<br>BMS-986249 1600 mg IV every 4 weeks (Q4W), up to 2 years                                                                                                                 |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1A: BMS-986249 2400 mg Monotherapy                  |
| Reporting group description:<br>BMS-986249 2400 mg IV every 4 weeks (Q4W), up to 2 years                                                                                                                 |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1A: BMS-986249 1600 mg Q8W Monotherapy              |
| Reporting group description:<br>BMS-986249 1600 mg IV every 8 weeks (Q8W), up to 2 years                                                                                                                 |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination        |
| Reporting group description:<br>BMS-986249 240 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years                                                                                        |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination         |
| Reporting group description:<br>BMS-986249 800 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years                                                                                        |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination  |
| Reporting group description:<br>BMS-986249 1200 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years                                                                                       |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination   |
| Reporting group description:<br>BMS-986249 800 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                                        |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination        |
| Reporting group description:<br>BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                                       |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination   |
| Reporting group description:<br>BMS-986249 1600 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                                       |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 2A Arm A: BMS-986249 240 mg Q3W + Nivo 360 mg Q3W   |
| Reporting group description:<br>BMS-986249 240 mg IV every 3 weeks (Q3W) + nivolumab 360 mg IV every 3 weeks (Q3W) (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W) (maintenance), up to 2 years. |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 2A Arm B: BMS-986249 800 mg + Nivo 480 mg Q4W       |
| Reporting group description:<br>BMS-986249 800 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                                        |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W  |
| Reporting group description:<br>BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years                                                                       |                                                          |
| Reporting group title                                                                                                                                                                                    | Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W |

Reporting group description:

Ipilimumab 3 mg/kg IV every 3 weeks (Q3W) + nivolumab 1 mg/kg IV Q3W (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W) monotherapy, up to 2 years.

|                       |                                            |
|-----------------------|--------------------------------------------|
| Reporting group title | Part 2A Arm E: Nivo 480 mg Q4W Monotherapy |
|-----------------------|--------------------------------------------|

Reporting group description:

Nivolumab 480 mg IV every 4 weeks (Q4W) monotherapy, up to 2 years.

|                       |                                                        |
|-----------------------|--------------------------------------------------------|
| Reporting group title | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W |
|-----------------------|--------------------------------------------------------|

Reporting group description:

BMS-986249 600 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years.

|                       |                                                  |
|-----------------------|--------------------------------------------------|
| Reporting group title | Part 2B: Cohort 1 (Advanced or Intermediate HCC) |
|-----------------------|--------------------------------------------------|

Reporting group description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years

|                       |                                     |
|-----------------------|-------------------------------------|
| Reporting group title | Part 2B: Cohort 2 (Metastatic CRPC) |
|-----------------------|-------------------------------------|

Reporting group description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

|                       |                                       |
|-----------------------|---------------------------------------|
| Reporting group title | Part 2B: Cohort 3 (Unresectable TNBC) |
|-----------------------|---------------------------------------|

Reporting group description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

|                            |                                                         |
|----------------------------|---------------------------------------------------------|
| Subject analysis set title | Part 2A Arm C: BMS-986249 1200 mg Q6W + Nivo 480 mg Q4W |
|----------------------------|---------------------------------------------------------|

|                           |              |
|---------------------------|--------------|
| Subject analysis set type | Per protocol |
|---------------------------|--------------|

Subject analysis set description:

BMS-986249 1200 mg IV every 6 weeks (Q6W) + nivolumab 480 mg IV every 4 weeks (Q4W)

|                            |                                                          |
|----------------------------|----------------------------------------------------------|
| Subject analysis set title | Part 2A Arm D: Ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W |
|----------------------------|----------------------------------------------------------|

|                           |              |
|---------------------------|--------------|
| Subject analysis set type | Per protocol |
|---------------------------|--------------|

Subject analysis set description:

Ipilimumab 3 mg/kg IV every 3 weeks (Q3W) + nivolumab 1 mg/kg IV Q3W (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W), monotherapy, up to 2 years.

|                            |                                                         |
|----------------------------|---------------------------------------------------------|
| Subject analysis set title | Part 2A Arm F: BMS-986249 1200 mg Q6W + Nivo 480 mg Q4W |
|----------------------------|---------------------------------------------------------|

|                           |              |
|---------------------------|--------------|
| Subject analysis set type | Per protocol |
|---------------------------|--------------|

Subject analysis set description:

BMS-986249 1200 mg IV every 6 weeks (Q6W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

|                            |                                                   |
|----------------------------|---------------------------------------------------|
| Subject analysis set title | Part 2B: Cohort 1 (Advanced or Intermediate HCC): |
|----------------------------|---------------------------------------------------|

|                           |              |
|---------------------------|--------------|
| Subject analysis set type | Per protocol |
|---------------------------|--------------|

Subject analysis set description:

BMS-986249 1200 mg IV every 6 weeks (Q6W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

|                            |                                    |
|----------------------------|------------------------------------|
| Subject analysis set title | Part 2B Cohort 2 (Metastatic CRPC) |
|----------------------------|------------------------------------|

|                           |              |
|---------------------------|--------------|
| Subject analysis set type | Per protocol |
|---------------------------|--------------|

Subject analysis set description:

BMS-986249 1200 mg IV every 6 weeks (Q6W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

|                            |                                       |
|----------------------------|---------------------------------------|
| Subject analysis set title | Part 2B: Cohort 3 (Unresectable TNBC) |
|----------------------------|---------------------------------------|

|                           |              |
|---------------------------|--------------|
| Subject analysis set type | Per protocol |
|---------------------------|--------------|

Subject analysis set description:

BMS-986249 1200 mg IV every 6 weeks (Q6W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years

**Primary: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) - Part 1 A and 1 B**

|                 |                                                                                                                         |
|-----------------|-------------------------------------------------------------------------------------------------------------------------|
| End point title | Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) - Part 1 A and 1 B <sup>[1][2]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------|

End point description:

Adverse Events (AEs):

Adverse events are any unwanted or harmful medical occurrences in a participant who receives a study drug or intervention. These events may or may not be related to the treatment.

Serious Adverse Events (SAEs):

Serious adverse events are adverse events that result in death, are life-threatening, require hospitalization or prolong existing hospitalization, cause significant disability or incapacity, or result in a birth defect.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From first dose until 100 days after last dose of study therapy (up to approximately 38 weeks)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No further statistical analysis done for this endpoint

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

| End point values                                | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy | Part 1A: BMS-986249 2400 mg Monotherapy |
|-------------------------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|-----------------------------------------|
| Subject group type                              | Reporting group                        | Reporting group                        | Reporting group                         | Reporting group                         |
| Number of subjects analysed                     | 6                                      | 11                                     | 10                                      | 1                                       |
| Units: Participants                             |                                        |                                        |                                         |                                         |
| Adverse events (AEs)                            | 6                                      | 11                                     | 10                                      | 1                                       |
| Serious adverse events (SAEs)                   | 4                                      | 8                                      | 8                                       | 1                                       |
| Adverse events (AEs) leading to discontinuation | 0                                      | 2                                      | 4                                       | 0                                       |

| End point values                                | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination | Part 1B: BMS-986249 800 mg Q4W + Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination |
|-------------------------------------------------|---------------------------------------------|---------------------------------------------------|---------------------------------------------------|---------------------------------------------------------|
| Subject group type                              | Reporting group                             | Reporting group                                   | Reporting group                                   | Reporting group                                         |
| Number of subjects analysed                     | 11                                          | 12                                                | 11                                                | 9                                                       |
| Units: Participants                             |                                             |                                                   |                                                   |                                                         |
| Adverse events (AEs)                            | 11                                          | 12                                                | 11                                                | 9                                                       |
| Serious adverse events (SAEs)                   | 7                                           | 8                                                 | 7                                                 | 7                                                       |
| Adverse events (AEs) leading to discontinuation | 2                                           | 3                                                 | 5                                                 | 4                                                       |

| End point values | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination | Part 1B: BMS-986249 1600 mg Q8W + Nivolumab Combination | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W |  |
|------------------|--------------------------------------------------------|---------------------------------------------------------|---------------------------------------------------------|--|
|------------------|--------------------------------------------------------|---------------------------------------------------------|---------------------------------------------------------|--|

| Subject group type                              | Reporting group | Reporting group | Reporting group |  |
|-------------------------------------------------|-----------------|-----------------|-----------------|--|
| Number of subjects analysed                     | 13              | 10              | 9               |  |
| Units: Participants                             |                 |                 |                 |  |
| Adverse events (AEs)                            | 13              | 10              | 9               |  |
| Serious adverse events (SAEs)                   | 10              | 8               | 7               |  |
| Adverse events (AEs) leading to discontinuation | 2               | 5               | 3               |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of participants with Adverse Events (AEs) meeting Protocol-Defined Dose-Limiting Toxicity (DLT) Criteria - Part 1 A and 1 B

|                 |                                                                                                                                                      |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Number of participants with Adverse Events (AEs) meeting Protocol-Defined Dose-Limiting Toxicity (DLT) Criteria - Part 1 A and 1 B <sup>[3][4]</sup> |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Dose-limiting toxicities (DLTs) were defined by the incidence, intensity, and duration of adverse events (AEs) possibly related to study treatment during the 5-week (35-day) DLT evaluation period for both BMS-986249 monotherapy and combination therapy. Participants who received at least 2 doses and completed or discontinued due to a DLT within this period were considered DLT-evaluable. Those who withdrew or received less than 2 doses for reasons other than a DLT were not DLT-evaluable and could be replaced. Any drug-related AE meeting DLT criteria resulted in discontinuation of study treatment. DLTs guided dose escalation and helped define the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D).

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From first dose until 5 weeks after first dose of study medicine (up to approximately 5 weeks)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No further statistical analysis done for this endpoint

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

| End point values            | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy | Part 1A: BMS-986249 2400 mg Monotherapy |
|-----------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|-----------------------------------------|
| Subject group type          | Reporting group                        | Reporting group                        | Reporting group                         | Reporting group                         |
| Number of subjects analysed | 6                                      | 11                                     | 10                                      | 1                                       |
| Units: Participants         | 0                                      | 0                                      | 1                                       | 0                                       |

| End point values            | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination |
|-----------------------------|---------------------------------------------|---------------------------------------------------|--------------------------------------------------|---------------------------------------------------------|
| Subject group type          | Reporting group                             | Reporting group                                   | Reporting group                                  | Reporting group                                         |
| Number of subjects analysed | 11                                          | 12                                                | 11                                               | 9                                                       |

|                     |   |   |   |   |
|---------------------|---|---|---|---|
| Units: Participants | 1 | 0 | 1 | 0 |
|---------------------|---|---|---|---|

|                             |                                                        |                                                        |                                                         |  |
|-----------------------------|--------------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------|--|
| <b>End point values</b>     | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W |  |
| Subject group type          | Reporting group                                        | Reporting group                                        | Reporting group                                         |  |
| Number of subjects analysed | 13                                                     | 10                                                     | 9                                                       |  |
| Units: Participants         | 0                                                      | 3                                                      | 0                                                       |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants who Died – Part 1 A and 1 B

|                 |                                                                                  |
|-----------------|----------------------------------------------------------------------------------|
| End point title | Number of Participants who Died – Part 1 A and 1 B <sup>[5]</sup> <sup>[6]</sup> |
|-----------------|----------------------------------------------------------------------------------|

End point description:

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From enrollment until the date of death from any cause (up to approximately 83 months)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No further statistical analysis done for this endpoint

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

|                             |                                        |                                        |                                         |                                         |
|-----------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|-----------------------------------------|
| <b>End point values</b>     | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy | Part 1A: BMS-986249 2400 mg Monotherapy |
| Subject group type          | Reporting group                        | Reporting group                        | Reporting group                         | Reporting group                         |
| Number of subjects analysed | 6                                      | 11                                     | 10                                      | 1                                       |
| Units: Participants         | 4                                      | 10                                     | 7                                       | 1                                       |

|                             |                                             |                                                   |                                                  |                                                         |
|-----------------------------|---------------------------------------------|---------------------------------------------------|--------------------------------------------------|---------------------------------------------------------|
| <b>End point values</b>     | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination |
| Subject group type          | Reporting group                             | Reporting group                                   | Reporting group                                  | Reporting group                                         |
| Number of subjects analysed | 11                                          | 12                                                | 11                                               | 9                                                       |
| Units: Participants         | 6                                           | 11                                                | 8                                                | 7                                                       |

| End point values            | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W |  |
|-----------------------------|--------------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------|--|
| Subject group type          | Reporting group                                        | Reporting group                                        | Reporting group                                         |  |
| Number of subjects analysed | 13                                                     | 10                                                     | 9                                                       |  |
| Units: Participants         | 8                                                      | 9                                                      | 4                                                       |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants with Shifts from Baseline in Laboratory Test results – Part 1 A and 1 B

|                        |                                                                                                                  |
|------------------------|------------------------------------------------------------------------------------------------------------------|
| End point title        | Number of Participants with Shifts from Baseline in Laboratory Test results – Part 1 A and 1 B <sup>[7][8]</sup> |
| End point description: | Number of Participants with Shifts from Baseline in Laboratory Tests                                             |
| End point type         | Primary                                                                                                          |
| End point timeframe:   | From first dose until 100 days after last dose of study therapy (up to approximately 38 weeks)                   |

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No further statistical analysis done for this endpoint

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

| End point values                            | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy | Part 1A: BMS-986249 2400 mg Monotherapy |
|---------------------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|-----------------------------------------|
| Subject group type                          | Reporting group                        | Reporting group                        | Reporting group                         | Reporting group                         |
| Number of subjects analysed                 | 6                                      | 11                                     | 9                                       | 1                                       |
| Units: Participants                         |                                        |                                        |                                         |                                         |
| HEMOGLOBIN                                  | 3                                      | 4                                      | 7                                       | 1                                       |
| PLATELET COUNT                              | 1                                      | 1                                      | 2                                       | 0                                       |
| LEUKOCYTES, LOCAL LAB                       | 1                                      | 0                                      | 1                                       | 0                                       |
| ABSOLUTE NEUTROPHIL COUNT DRV               | 0                                      | 0                                      | 0                                       | 0                                       |
| LYMPHOCYTES (ABSOLUTE)                      | 2                                      | 1                                      | 3                                       | 0                                       |
| LYMPHOCYTES (ABSOLUTE), LOCAL LAB           | 2                                      | 7                                      | 6                                       | 0                                       |
| CREATININE, LOCAL LAB                       | 0                                      | 4                                      | 1                                       | 0                                       |
| ALKALINE PHOSPHATASE (ALP) LOCAL LAB        | 1                                      | 7                                      | 1                                       | 1                                       |
| ALANINE AMINOTRANSFERASE (ALT), LOCAL LAB   | 2                                      | 4                                      | 2                                       | 0                                       |
| ASPARTATE AMINOTRANSFERASE (AST), LOCAL LAB | 2                                      | 7                                      | 3                                       | 1                                       |

|                             |   |   |   |   |
|-----------------------------|---|---|---|---|
| BILIRUBIN, TOTAL, LOCAL LAB | 2 | 1 | 1 | 1 |
|-----------------------------|---|---|---|---|

| End point values                            | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination |
|---------------------------------------------|---------------------------------------------|---------------------------------------------------|--------------------------------------------------|---------------------------------------------------------|
| Subject group type                          | Reporting group                             | Reporting group                                   | Reporting group                                  | Reporting group                                         |
| Number of subjects analysed                 | 11                                          | 12                                                | 11                                               | 9                                                       |
| Units: Participants                         |                                             |                                                   |                                                  |                                                         |
| HEMOGLOBIN                                  | 4                                           | 10                                                | 9                                                | 6                                                       |
| PLATELET COUNT                              | 0                                           | 0                                                 | 3                                                | 0                                                       |
| LEUKOCYTES, LOCAL LAB                       | 2                                           | 3                                                 | 4                                                | 0                                                       |
| ABSOLUTE NEUTROPHIL COUNT DRV               | 2                                           | 0                                                 | 4                                                | 0                                                       |
| LYMPHOCYTES (ABSOLUTE)                      | 0                                           | 0                                                 | 1                                                | 0                                                       |
| LYMPHOCYTES (ABSOLUTE), LOCAL LAB           | 3                                           | 6                                                 | 5                                                | 5                                                       |
| CREATININE, LOCAL LAB                       | 1                                           | 1                                                 | 1                                                | 1                                                       |
| ALKALINE PHOSPHATASE (ALP) LOCAL LAB        | 3                                           | 5                                                 | 4                                                | 6                                                       |
| ALANINE AMINOTRANSFERASE (ALT), LOCAL LAB   | 2                                           | 4                                                 | 4                                                | 4                                                       |
| ASPARTATE AMINOTRANSFERASE (AST), LOCAL LAB | 3                                           | 4                                                 | 6                                                | 4                                                       |
| BILIRUBIN, TOTAL, LOCAL LAB                 | 1                                           | 1                                                 | 5                                                | 2                                                       |

| End point values                            | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W |  |
|---------------------------------------------|--------------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------|--|
| Subject group type                          | Reporting group                                        | Reporting group                                        | Reporting group                                         |  |
| Number of subjects analysed                 | 13                                                     | 10                                                     | 9                                                       |  |
| Units: Participants                         |                                                        |                                                        |                                                         |  |
| HEMOGLOBIN                                  | 7                                                      | 7                                                      | 4                                                       |  |
| PLATELET COUNT                              | 2                                                      | 3                                                      | 1                                                       |  |
| LEUKOCYTES, LOCAL LAB                       | 2                                                      | 3                                                      | 1                                                       |  |
| ABSOLUTE NEUTROPHIL COUNT DRV               | 1                                                      | 2                                                      | 2                                                       |  |
| LYMPHOCYTES (ABSOLUTE)                      | 2                                                      | 0                                                      | 2                                                       |  |
| LYMPHOCYTES (ABSOLUTE), LOCAL LAB           | 1                                                      | 4                                                      | 6                                                       |  |
| CREATININE, LOCAL LAB                       | 3                                                      | 5                                                      | 2                                                       |  |
| ALKALINE PHOSPHATASE (ALP) LOCAL LAB        | 5                                                      | 6                                                      | 2                                                       |  |
| ALANINE AMINOTRANSFERASE (ALT), LOCAL LAB   | 5                                                      | 4                                                      | 3                                                       |  |
| ASPARTATE AMINOTRANSFERASE (AST), LOCAL LAB | 5                                                      | 5                                                      | 3                                                       |  |
| BILIRUBIN, TOTAL, LOCAL LAB                 | 4                                                      | 2                                                      | 3                                                       |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants with Treatment-Related Grade 3-5 Adverse Events (AEs) Within 24 weeks – Part 2 A Arms C, D and F, and Part 2 B

|                 |                                                                                                                                                          |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Number of Participants with Treatment-Related Grade 3-5 Adverse Events (AEs) Within 24 weeks – Part 2 A Arms C, D and F, and Part 2 B <sup>[9][10]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Adverse Events (AEs):

Adverse events are any unwanted or harmful medical occurrences in a participant who receives a study drug or intervention. These events may or may not be related to the treatment.

Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; no intervention needed.

Grade 2: Moderate; minimal, local, or noninvasive intervention indicated; limiting age-appropriate activities.

Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling.

Grade 4: Life-threatening consequences; urgent intervention required.

Grade 5: Death related to the adverse event.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From first dose until 24 weeks after first dose (up to approximately 24 weeks)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No further statistical analysis done for this endpoint

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

| End point values            | Part 2A Arm C:<br>BMS-986249<br>1200 mg Q8W<br>+ Nivo 480 mg<br>Q4W | Part 2A Arm D:<br>ipilimumab 3<br>mg/kg Q3W +<br>Nivo 1 mg/kg<br>Q3W | Part 2A Arm F:<br>BMS-986249<br>600 mg Q4W +<br>Nivo 480 mg<br>Q4W | Part 2B: Cohort<br>1 (Advanced or<br>Intermediate<br>HCC) |
|-----------------------------|---------------------------------------------------------------------|----------------------------------------------------------------------|--------------------------------------------------------------------|-----------------------------------------------------------|
| Subject group type          | Reporting group                                                     | Reporting group                                                      | Reporting group                                                    | Reporting group                                           |
| Number of subjects analysed | 58                                                                  | 59                                                                   | 36                                                                 | 5                                                         |
| Units: Participants         | 24                                                                  | 18                                                                   | 14                                                                 | 4                                                         |

| End point values            | Part 2B: Cohort<br>2 (Metastatic<br>CRPC) | Part 2B: Cohort<br>3<br>(Unresectable<br>TNBC) |  |  |
|-----------------------------|-------------------------------------------|------------------------------------------------|--|--|
| Subject group type          | Reporting group                           | Reporting group                                |  |  |
| Number of subjects analysed | 41                                        | 45                                             |  |  |
| Units: Participants         | 13                                        | 11                                             |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Objective Response Rate (ORR) as Assessed by Investigator - Part 2 A Arm C and F

|                 |                                                                                                      |
|-----------------|------------------------------------------------------------------------------------------------------|
| End point title | Objective Response Rate (ORR) as Assessed by Investigator - Part 2 A Arm C and F <sup>[11][12]</sup> |
|-----------------|------------------------------------------------------------------------------------------------------|

End point description:

Objective response rate (ORR) is defined as the percent of participants whose best overall response (BOR) is either complete response (CR) or partial response (PR) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1:

Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must also have reduction in the short axis to <10mm.

Partial Response (PR): At least a30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From randomization until progression or death from any cause (up to approximately 83 months)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No further statistical analysis done for this endpoint

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

|                                   |                                                                     |                                                                    |  |  |
|-----------------------------------|---------------------------------------------------------------------|--------------------------------------------------------------------|--|--|
| <b>End point values</b>           | Part 2A Arm C:<br>BMS-986249<br>1200 mg Q8W<br>+ Nivo 480 mg<br>Q4W | Part 2A Arm F:<br>BMS-986249<br>600 mg Q4W +<br>Nivo 480 mg<br>Q4W |  |  |
| Subject group type                | Reporting group                                                     | Reporting group                                                    |  |  |
| Number of subjects analysed       | 58                                                                  | 36                                                                 |  |  |
| Units: Percentage of participants |                                                                     |                                                                    |  |  |
| number (confidence interval 95%)  | 36.2 (24.0 to<br>49.9)                                              | 52.8 (35.5 to<br>69.6)                                             |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Time to Deterioration in Part 2A (Arm C, D and F)

|                 |                                                                   |
|-----------------|-------------------------------------------------------------------|
| End point title | Time to Deterioration in Part 2A (Arm C, D and F) <sup>[13]</sup> |
|-----------------|-------------------------------------------------------------------|

End point description:

TTD in Global Health Status/QoL and Physical Functioning will be defined as the time from randomization until a clinically meaningful decline (i.e., reduction  $\geq 10$  points) from baseline in EORTC QLQ-C30 global health/quality of life subscale score and Physical Functioning Scale score.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Approximately up to 6 months

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

|                                  |                                                                     |                                                                      |                                                                    |  |
|----------------------------------|---------------------------------------------------------------------|----------------------------------------------------------------------|--------------------------------------------------------------------|--|
| <b>End point values</b>          | Part 2A Arm C:<br>BMS-986249<br>1200 mg Q8W<br>+ Nivo 480 mg<br>Q4W | Part 2A Arm D:<br>ipilimumab 3<br>mg/kg Q3W +<br>Nivo 1 mg/kg<br>Q3W | Part 2A Arm F:<br>BMS-986249<br>600 mg Q4W +<br>Nivo 480 mg<br>Q4W |  |
| Subject group type               | Reporting group                                                     | Reporting group                                                      | Reporting group                                                    |  |
| Number of subjects analysed      | 58                                                                  | 59                                                                   | 36                                                                 |  |
| Units: Months                    |                                                                     |                                                                      |                                                                    |  |
| median (confidence interval 95%) | 3.52 (1.87 to<br>5.29)                                              | 4.37 (1.51 to<br>5.78)                                               | 2.79 (1.22 to<br>5.65)                                             |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Safety Related Events in Part 2A (Arm C, D and F) and 2B

|                 |                                                                          |
|-----------------|--------------------------------------------------------------------------|
| End point title | Safety Related Events in Part 2A (Arm C, D and F) and 2B <sup>[14]</sup> |
|-----------------|--------------------------------------------------------------------------|

End point description:

Adverse Events (AEs):

Adverse events are any unwanted or harmful medical occurrences in a participant who receives a study drug or intervention. These events may or may not be related to the treatment.

Serious Adverse Events (SAEs):

Serious adverse events are adverse events that result in death, are life-threatening, require hospitalization or prolong existing hospitalization, cause significant disability or incapacity, or result in a birth defect.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From first dose until 100 days after last dose of study therapy (up to approximately 38 weeks)

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

|                                |                                                                     |                                                                      |                                                                    |                                                           |
|--------------------------------|---------------------------------------------------------------------|----------------------------------------------------------------------|--------------------------------------------------------------------|-----------------------------------------------------------|
| <b>End point values</b>        | Part 2A Arm C:<br>BMS-986249<br>1200 mg Q8W<br>+ Nivo 480 mg<br>Q4W | Part 2A Arm D:<br>ipilimumab 3<br>mg/kg Q3W +<br>Nivo 1 mg/kg<br>Q3W | Part 2A Arm F:<br>BMS-986249<br>600 mg Q4W +<br>Nivo 480 mg<br>Q4W | Part 2B: Cohort<br>1 (Advanced or<br>Intermediate<br>HCC) |
| Subject group type             | Reporting group                                                     | Reporting group                                                      | Reporting group                                                    | Reporting group                                           |
| Number of subjects analysed    | 57                                                                  | 58                                                                   | 36                                                                 | 5                                                         |
| Units: Template                |                                                                     |                                                                      |                                                                    |                                                           |
| Adverse Events                 | 57                                                                  | 57                                                                   | 35                                                                 | 5                                                         |
| Serious Adverse Events         | 41                                                                  | 28                                                                   | 20                                                                 | 5                                                         |
| AEs leading to discontinuation | 24                                                                  | 25                                                                   | 20                                                                 | 4                                                         |
| Deaths                         | 27                                                                  | 24                                                                   | 10                                                                 | 4                                                         |

|                         |                                           |                                                |  |  |
|-------------------------|-------------------------------------------|------------------------------------------------|--|--|
| <b>End point values</b> | Part 2B: Cohort<br>2 (Metastatic<br>CRPC) | Part 2B: Cohort<br>3<br>(Unresectable<br>TNBC) |  |  |
|-------------------------|-------------------------------------------|------------------------------------------------|--|--|

|                                |                 |                 |  |  |
|--------------------------------|-----------------|-----------------|--|--|
| Subject group type             | Reporting group | Reporting group |  |  |
| Number of subjects analysed    | 41              | 45              |  |  |
| Units: Template                |                 |                 |  |  |
| Adverse Events                 | 40              | 45              |  |  |
| Serious Adverse Events         | 29              | 25              |  |  |
| AEs leading to discontinuation | 13              | 13              |  |  |
| Deaths                         | 26              | 28              |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: BOR of PSA and PCWG3 Response Rate in Part 2B Cohort 2

|                 |                                                                        |
|-----------------|------------------------------------------------------------------------|
| End point title | BOR of PSA and PCWG3 Response Rate in Part 2B Cohort 2 <sup>[15]</sup> |
|-----------------|------------------------------------------------------------------------|

End point description:

Best Overall Response (BOR) is defined as the best response recorded from the start of randomization or first dosing date until the date of objectively documented PD based on RECIST v1.1 criteria or PCWG3 (for prostate cancer), or the date of subsequent therapy (including tumor directed radiotherapy and tumor-directed surgery which are not for palliative purpose), whichever occurs first.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From first dose (Parts 1 A and B) or randomization (Part 2 B) progression or death from any cause (up to approximately 83 months)

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

|                                   |                                     |  |  |  |
|-----------------------------------|-------------------------------------|--|--|--|
| <b>End point values</b>           | Part 2B: Cohort 2 (Metastatic CRPC) |  |  |  |
| Subject group type                | Reporting group                     |  |  |  |
| Number of subjects analysed       | 41                                  |  |  |  |
| Units: Percentage of participants |                                     |  |  |  |
| number (confidence interval 95%)  |                                     |  |  |  |
| PSA Response Rate                 | 14.6 (5.6 to 29.2)                  |  |  |  |
| PCWG3 Response Rate               | 9.8 (2.7 to 23.1)                   |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Progression Free Survival

|                 |                                           |
|-----------------|-------------------------------------------|
| End point title | Progression Free Survival <sup>[16]</sup> |
|-----------------|-------------------------------------------|

End point description:

Defined as the time between the date of randomization (Part 2A), or first dosing for Part 1 and supplemental analysis in Part 2A, and the date of first documented tumor progression, based on

investigator assessments (per RECIST v1.1 criteria or PCWG3), or death due to any cause, whichever occurs first.

Here "-99999 and 99999" = NA

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From first dose (Parts 1 A and B) or randomization (Part 2 B) progression or death from any cause (up to approximately 83 months)

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

|                                  |                                        |                                        |                                         |                                         |
|----------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|-----------------------------------------|
| <b>End point values</b>          | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy | Part 1A: BMS-986249 2400 mg Monotherapy |
| Subject group type               | Reporting group                        | Reporting group                        | Reporting group                         | Reporting group                         |
| Number of subjects analysed      | 6                                      | 11                                     | 10                                      | 1                                       |
| Units: Months                    |                                        |                                        |                                         |                                         |
| median (confidence interval 95%) | 1.74 (1.41 to 99999)                   | 1.77 (1.15 to 1.84)                    | 1.69 (0.53 to 3.25)                     | 3.55 (-99999 to 99999)                  |

|                                  |                                             |                                                   |                                                  |                                                         |
|----------------------------------|---------------------------------------------|---------------------------------------------------|--------------------------------------------------|---------------------------------------------------------|
| <b>End point values</b>          | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination |
| Subject group type               | Reporting group                             | Reporting group                                   | Reporting group                                  | Reporting group                                         |
| Number of subjects analysed      | 11                                          | 12                                                | 11                                               | 9                                                       |
| Units: Months                    |                                             |                                                   |                                                  |                                                         |
| median (confidence interval 95%) | 1.68 (1.05 to 99999)                        | 2.33 (1.68 to 3.32)                               | 1.71 (0.85 to 14.23)                             | 3.32 (1.22 to 4.40)                                     |

|                                  |                                                        |                                                   |                                                        |                                                         |
|----------------------------------|--------------------------------------------------------|---------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------|
| <b>End point values</b>          | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination | Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W |
| Subject group type               | Reporting group                                        | Reporting group                                   | Reporting group                                        | Reporting group                                         |
| Number of subjects analysed      | 13                                                     | 9                                                 | 10                                                     | 58                                                      |
| Units: Months                    |                                                        |                                                   |                                                        |                                                         |
| median (confidence interval 95%) | 1.92 (0.59 to 7.13)                                    | 1.91 (1.02 to 99999)                              | 4.35 (0.92 to 12.45)                                   | 6.51 (4.90 to 12.52)                                    |

|                         |                                                          |                                                        |                                                  |                                     |
|-------------------------|----------------------------------------------------------|--------------------------------------------------------|--------------------------------------------------|-------------------------------------|
| <b>End point values</b> | Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W | Part 2B: Cohort 1 (Advanced or Intermediate HCC) | Part 2B: Cohort 2 (Metastatic CRPC) |
|-------------------------|----------------------------------------------------------|--------------------------------------------------------|--------------------------------------------------|-------------------------------------|

|                                  |                     |                       |                      |                     |
|----------------------------------|---------------------|-----------------------|----------------------|---------------------|
| Subject group type               | Reporting group     | Reporting group       | Reporting group      | Reporting group     |
| Number of subjects analysed      | 59                  | 36                    | 5                    | 41                  |
| Units: Months                    |                     |                       |                      |                     |
| median (confidence interval 95%) | 4.73 (2.89 to 9.76) | 10.38 (6.74 to 99999) | 2.99 (1.77 to 99999) | 5.62 (3.68 to 8.28) |

|                                  |                                          |  |  |  |
|----------------------------------|------------------------------------------|--|--|--|
| <b>End point values</b>          | Part 2B: Cohort 3<br>(Unresectable TNBC) |  |  |  |
| Subject group type               | Reporting group                          |  |  |  |
| Number of subjects analysed      | 45                                       |  |  |  |
| Units: Months                    |                                          |  |  |  |
| median (confidence interval 95%) | 3.35 (1.84 to 5.36)                      |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Duration of Response

|                 |                                      |
|-----------------|--------------------------------------|
| End point title | Duration of Response <sup>[17]</sup> |
|-----------------|--------------------------------------|

End point description:

Defined as the time between the date of first documented response (CR or PR) to the date of the first documented tumor progression, as determined by RECIST v1.1 or PCWG3 criteria, or death due to any cause, whichever occurs first. Subjects who start subsequent therapy without a prior reported progression will be censored at the last evaluable tumor assessments prior to initiation of the subsequent anticancer therapy. Subjects who die without a reported prior progression will be considered to have progressed on the date of their death. Subjects who neither progress nor die, DOR will be censored on the date of their last evaluable tumor assessment. DOR will be evaluated for responders (confirmed CR or PR) only.

Here "99999" = NA

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From first dose (Parts 1 A and B) or randomization (Part 2 B) progression or death from any cause (up to approximately 83 months)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

|                               |                                        |                                        |                                         |                                         |
|-------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|-----------------------------------------|
| <b>End point values</b>       | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy | Part 1A: BMS-986249 2400 mg Monotherapy |
| Subject group type            | Reporting group                        | Reporting group                        | Reporting group                         | Reporting group                         |
| Number of subjects analysed   | 0 <sup>[18]</sup>                      | 0 <sup>[19]</sup>                      | 0 <sup>[20]</sup>                       | 0 <sup>[21]</sup>                       |
| Units: Months                 |                                        |                                        |                                         |                                         |
| median (full range (min-max)) | ( to )                                 | ( to )                                 | ( to )                                  | ( to )                                  |

Notes:

- [18] - No subjects with events
- [19] - No subjects with events
- [20] - No subjects with events
- [21] - No subjects with events

| End point values              | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination |
|-------------------------------|---------------------------------------------|---------------------------------------------------|--------------------------------------------------|---------------------------------------------------------|
| Subject group type            | Reporting group                             | Reporting group                                   | Reporting group                                  | Reporting group                                         |
| Number of subjects analysed   | 0 <sup>[22]</sup>                           | 0 <sup>[23]</sup>                                 | 2                                                | 0 <sup>[24]</sup>                                       |
| Units: Months                 |                                             |                                                   |                                                  |                                                         |
| median (full range (min-max)) | ( to )                                      | ( to )                                            | 99999 (12.48 to 99999)                           | ( to )                                                  |

Notes:

- [22] - No subjects with events
- [23] - No subjects with events
- [24] - No subjects with events

| End point values              | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination | Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W |
|-------------------------------|--------------------------------------------------------|---------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------|
| Subject group type            | Reporting group                                        | Reporting group                                   | Reporting group                                        | Reporting group                                         |
| Number of subjects analysed   | 3                                                      | 3                                                 | 3                                                      | 21                                                      |
| Units: Months                 |                                                        |                                                   |                                                        |                                                         |
| median (full range (min-max)) | 15.80 (1.68 to 99999)                                  | 99999 (1.74 to 99999)                             | 99999 (8.97 to 99999)                                  | 26.84 (7.85 to 99999)                                   |

| End point values              | Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W | Part 2B: Cohort 1 (Advanced or Intermediate HCC) | Part 2B: Cohort 2 (Metastatic CRPC) |
|-------------------------------|----------------------------------------------------------|--------------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type            | Reporting group                                          | Reporting group                                        | Reporting group                                  | Reporting group                     |
| Number of subjects analysed   | 21                                                       | 19                                                     | 0 <sup>[25]</sup>                                | 4                                   |
| Units: Months                 |                                                          |                                                        |                                                  |                                     |
| median (full range (min-max)) | 99999 (7.2 to 99999)                                     | 99999 (6.47 to 99999)                                  | ( to )                                           | 99999 (99999 to 99999)              |

Notes:

- [25] - No subjects with events

| End point values              | Part 2B: Cohort 3 (Unresectable TNBC) |  |  |  |
|-------------------------------|---------------------------------------|--|--|--|
| Subject group type            | Reporting group                       |  |  |  |
| Number of subjects analysed   | 7                                     |  |  |  |
| Units: Months                 |                                       |  |  |  |
| median (full range (min-max)) | 21.49 (3.68 to 99999)                 |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Time to Response

|                 |                                  |
|-----------------|----------------------------------|
| End point title | Time to Response <sup>[26]</sup> |
|-----------------|----------------------------------|

End point description:

From first dose (Parts 1 A and B) or randomization (Part 2 B) progression or death from any cause (up to approximately 83 months)

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From first dose to first objective response (Approximately up to 3 Months)

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

| End point values              | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy | Part 1A: BMS-986249 2400 mg Monotherapy |
|-------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|-----------------------------------------|
| Subject group type            | Reporting group                        | Reporting group                        | Reporting group                         | Reporting group                         |
| Number of subjects analysed   | 0 <sup>[27]</sup>                      | 0 <sup>[28]</sup>                      | 0 <sup>[29]</sup>                       | 0 <sup>[30]</sup>                       |
| Units: Months                 |                                        |                                        |                                         |                                         |
| median (full range (min-max)) | ( to )                                 | ( to )                                 | ( to )                                  | ( to )                                  |

Notes:

[27] - No Subjects with Events

[28] - No Subjects with Events

[29] - No Subjects with Events

[30] - No Subjects with Events

| End point values              | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination |
|-------------------------------|---------------------------------------------|---------------------------------------------------|--------------------------------------------------|---------------------------------------------------------|
| Subject group type            | Reporting group                             | Reporting group                                   | Reporting group                                  | Reporting group                                         |
| Number of subjects analysed   | 0 <sup>[31]</sup>                           | 0 <sup>[32]</sup>                                 | 2                                                | 0 <sup>[33]</sup>                                       |
| Units: Months                 |                                             |                                                   |                                                  |                                                         |
| median (full range (min-max)) | ( to )                                      | ( to )                                            | 2.76 (1.8 to 3.7)                                | ( to )                                                  |

Notes:

[31] - No Subjects with Events

[32] - No Subjects with Events

[33] - No Subjects with Events

| End point values | Part 1B: BMS-986249 800 | Part 1B: BMS-986249 1200 | Part 1B: BMS-986249 1600 | Part 2A Arm C: BMS-986249 |
|------------------|-------------------------|--------------------------|--------------------------|---------------------------|
|------------------|-------------------------|--------------------------|--------------------------|---------------------------|

|                               | mg Q8W + Nivolumab Combination | mg Q8W+ Nivo Combination | mg Q8W+ Nivolumab Combination | 1200 mg Q8W + Nivo 480 mg Q4W |
|-------------------------------|--------------------------------|--------------------------|-------------------------------|-------------------------------|
| Subject group type            | Reporting group                | Reporting group          | Reporting group               | Reporting group               |
| Number of subjects analysed   | 3                              | 3                        | 3                             | 21                            |
| Units: Months                 |                                |                          |                               |                               |
| median (full range (min-max)) | 1.74 (1.7 to 3.9)              | 3.48 (3.48 to 5.4)       | 4.01 (3.5 to 4.3)             | 2.86 (2.1 to 8.6)             |

| End point values              | Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W | Part 2B: Cohort 1 (Advanced or Intermediate HCC) | Part 2B: Cohort 2 (Metastatic CRPC) |
|-------------------------------|----------------------------------------------------------|--------------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type            | Reporting group                                          | Reporting group                                        | Reporting group                                  | Reporting group                     |
| Number of subjects analysed   | 21                                                       | 19                                                     | 0 <sup>[34]</sup>                                | 4                                   |
| Units: Months                 |                                                          |                                                        |                                                  |                                     |
| median (full range (min-max)) | 2.83 (2.0 to 26.4)                                       | 2.83 (2.66 to 4.44)                                    | ( to )                                           | 2.84 (1.7 to 3.9)                   |

Notes:

[34] - No Subjects with Events

| End point values              | Part 2B: Cohort 3 (Unresectable TNBC) |  |  |  |
|-------------------------------|---------------------------------------|--|--|--|
| Subject group type            | Reporting group                       |  |  |  |
| Number of subjects analysed   | 7                                     |  |  |  |
| Units: Months                 |                                       |  |  |  |
| median (full range (min-max)) | 1.87 (1.74 to 2.76)                   |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: ORR by Investigator

|                 |                                     |
|-----------------|-------------------------------------|
| End point title | ORR by Investigator <sup>[35]</sup> |
|-----------------|-------------------------------------|

End point description:

Objective response rate (ORR) is defined as the percent of participants whose best overall response (BOR) is either complete response (CR) or partial response (PR) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 or Prostate Cancer Working Group (PCWG) 3. For both RECIST v1.1 and PCWG3:

Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must also have reduction in the short axis to <10mm.

Partial Response (PR): At least a30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From first dose (Parts 1 A and B) or randomization (Part 2 B) progression or death from any cause (up to approximately 83 months)

Notes:

[35] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

| End point values                  | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy | Part 1A: BMS-986249 2400 mg Monotherapy |
|-----------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|-----------------------------------------|
| Subject group type                | Reporting group                        | Reporting group                        | Reporting group                         | Reporting group                         |
| Number of subjects analysed       | 6                                      | 11                                     | 10                                      | 1                                       |
| Units: Percentage of participants |                                        |                                        |                                         |                                         |
| number (confidence interval 95%)  | 0 (0.0 to 45.9)                        | 0 (0.0 to 28.5)                        | 0 (0.0 to 30.8)                         | 0 (0.0 to 97.5)                         |

| End point values                  | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination |
|-----------------------------------|---------------------------------------------|---------------------------------------------------|--------------------------------------------------|---------------------------------------------------------|
| Subject group type                | Reporting group                             | Reporting group                                   | Reporting group                                  | Reporting group                                         |
| Number of subjects analysed       | 11                                          | 12                                                | 11                                               | 9                                                       |
| Units: Percentage of participants |                                             |                                                   |                                                  |                                                         |
| number (confidence interval 95%)  | 0 (0.0 to 28.5)                             | 0 (0.0 to 26.5)                                   | 18.2 (2.3 to 51.8)                               | 0 (0.0 to 33.6)                                         |

| End point values                  | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination | Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W |
|-----------------------------------|--------------------------------------------------------|---------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------|
| Subject group type                | Reporting group                                        | Reporting group                                   | Reporting group                                        | Reporting group                                         |
| Number of subjects analysed       | 13                                                     | 9                                                 | 10                                                     | 58                                                      |
| Units: Percentage of participants |                                                        |                                                   |                                                        |                                                         |
| number (confidence interval 95%)  | 23.1 (5.0 to 53.8)                                     | 33.3 (7.5 to 70.1)                                | 30.0 (6.7 to 65.2)                                     | 36.2 (24.0 to 49.9)                                     |

| End point values                  | Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W | Part 2B: Cohort 1 (Advanced or Intermediate HCC) | Part 2B: Cohort 2 (Metastatic CRPC) |
|-----------------------------------|----------------------------------------------------------|--------------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type                | Reporting group                                          | Reporting group                                        | Reporting group                                  | Reporting group                     |
| Number of subjects analysed       | 59                                                       | 36                                                     | 5                                                | 41                                  |
| Units: Percentage of participants |                                                          |                                                        |                                                  |                                     |
| number (confidence interval 95%)  | 35.6 (23.6 to 49.1)                                      | 52.8 (35.5 to 69.6)                                    | 0 (0.0 to 52.2)                                  | 9.8 (2.7 to 23.1)                   |

|                                   |                                          |  |  |  |
|-----------------------------------|------------------------------------------|--|--|--|
| <b>End point values</b>           | Part 2B: Cohort 3<br>(Unresectable TNBC) |  |  |  |
| Subject group type                | Reporting group                          |  |  |  |
| Number of subjects analysed       | 45                                       |  |  |  |
| Units: Percentage of participants |                                          |  |  |  |
| number (confidence interval 95%)  | 15.6 (6.5 to 29.5)                       |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Objective Response Rate (ORR) as Assessed by Investigator - Part 1 A, 1B, 2A (Arms C,D,F) and 2B

|                 |                                                                                                                  |
|-----------------|------------------------------------------------------------------------------------------------------------------|
| End point title | Objective Response Rate (ORR) as Assessed by Investigator - Part 1 A, 1B, 2A (Arms C,D,F) and 2B <sup>[36]</sup> |
|-----------------|------------------------------------------------------------------------------------------------------------------|

End point description:

Objective response rate (ORR) is defined as the percent of participants whose best overall response (BOR) is either complete response (CR) or partial response (PR) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 or Prostate Cancer Working Group (PCWG) 3. For both RECIST v1.1 and PCWG3:

Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must also have reduction in the short axis to <10mm.

Partial Response (PR): At least a30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From first dose (Parts 1 A and B) or randomization (Part 2 B) progression or death from any cause (up to approximately 83 months)

Notes:

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

|                                   |                                        |                                        |                                         |                                         |
|-----------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|-----------------------------------------|
| <b>End point values</b>           | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy | Part 1A: BMS-986249 2400 mg Monotherapy |
| Subject group type                | Reporting group                        | Reporting group                        | Reporting group                         | Reporting group                         |
| Number of subjects analysed       | 6                                      | 11                                     | 10                                      | 1                                       |
| Units: Percentage of participants |                                        |                                        |                                         |                                         |
| number (confidence interval 95%)  | 0 (0.0 to 45.9)                        | 0 (0.0 to 28.5)                        | 0 (0.0 to 30.8)                         | 0 (0.0 to 97.5)                         |

|                         |                                 |                                  |                                      |                                   |
|-------------------------|---------------------------------|----------------------------------|--------------------------------------|-----------------------------------|
| <b>End point values</b> | Part 1A: BMS-986249 1600 mg Q8W | Part 1B: BMS-986249 240 mg Q4W + | Part 1B: BMS-986249 800 mg Q4W+ Nivo | Part 1B: BMS-986249 1200 mg Q4W + |
|-------------------------|---------------------------------|----------------------------------|--------------------------------------|-----------------------------------|

|                                   | Monotherapy     | Nivo Combination | Combination        | Nivolumab Combination |
|-----------------------------------|-----------------|------------------|--------------------|-----------------------|
| Subject group type                | Reporting group | Reporting group  | Reporting group    | Reporting group       |
| Number of subjects analysed       | 11              | 12               | 11                 | 9                     |
| Units: Percentage of participants |                 |                  |                    |                       |
| number (confidence interval 95%)  | 0 (0.0 to 28.5) | 0 (0.0 to 26.5)  | 18.2 (2.3 to 51.8) | 0 (0.0 to 33.6)       |

| End point values                  | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination | Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W |
|-----------------------------------|--------------------------------------------------------|---------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------|
| Subject group type                | Reporting group                                        | Reporting group                                   | Reporting group                                        | Reporting group                                         |
| Number of subjects analysed       | 13                                                     | 9                                                 | 10                                                     | 3                                                       |
| Units: Percentage of participants |                                                        |                                                   |                                                        |                                                         |
| number (confidence interval 95%)  | 23.1 (5.0 to 53.8)                                     | 33.3 (7.5 to 70.1)                                | 30.0 (6.7 to 65.2)                                     | 31.0 (19.5 to 44.5)                                     |

| End point values                  | Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W |  |  |
|-----------------------------------|----------------------------------------------------------|--------------------------------------------------------|--|--|
| Subject group type                | Reporting group                                          | Reporting group                                        |  |  |
| Number of subjects analysed       | 59                                                       | 36                                                     |  |  |
| Units: Percentage of participants |                                                          |                                                        |  |  |
| number (confidence interval 95%)  | 27.1 (16.4 to 40.3)                                      | 50.0 (32.9 to 67.1)                                    |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cmax and Ctau of BMS-986249 - Part 1 A and B, Part 2 A Arms C and F, Part 2 B

|                 |                                                                                               |
|-----------------|-----------------------------------------------------------------------------------------------|
| End point title | Cmax and Ctau of BMS-986249 - Part 1 A and B, Part 2 A Arms C and F, Part 2 B <sup>[37]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------|

End point description:

Cmax: The highest concentration of BMS-986249 in the blood after dosing.

Ctau: The concentration of BMS-986249 in the blood at the end of a dosing interval, just before the next dose

Here "99999" = NA

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

On Cycle 1 Day 1, Cycle 3 Day 1, Cycle 4 Day 1, Cycle 5 Day 1 (each cycle=28 days)

Notes:

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

| End point values                                    | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy | Part 1A: BMS-986249 2400 mg Monotherapy |
|-----------------------------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|-----------------------------------------|
| Subject group type                                  | Reporting group                        | Reporting group                        | Reporting group                         | Reporting group                         |
| Number of subjects analysed                         | 5                                      | 11                                     | 10                                      | 1                                       |
| Units: ng/mL                                        |                                        |                                        |                                         |                                         |
| geometric mean (geometric coefficient of variation) |                                        |                                        |                                         |                                         |
| Cmax Cycle 1 Day 1                                  | 398 (± 24)                             | 1451 (± 39)                            | 3569 (± 27)                             | 4965 (± 99999)                          |
| Cmax C3D1                                           | 99999 (± 99999)                        | 99999 (± 99999)                        | 99999 (± 99999)                         | 99999 (± 99999)                         |
| Cmax Cycle 4 Day 1                                  | 432 (± 55)                             | 1425 (± 14)                            | 5299 (± 99999)                          | 3910 (± 99999)                          |
| Cmax C5D1                                           | 99999 (± 99999)                        | 99999 (± 99999)                        | 99999 (± 99999)                         | 99999 (± 99999)                         |
| Ctau Cycle 1 Day 1                                  | 7.69 (± 4151)                          | 174 (± 71)                             | 344 (± 418)                             | 385 (± 99999)                           |
| Ctau C3D1                                           | 99999 (± 99999)                        | 99999 (± 99999)                        | 99999 (± 99999)                         | 99999 (± 99999)                         |
| Ctau Cycle 4 Day 1                                  | 51.6 (± 255)                           | 1425 (± 14)                            | 99999 (± 99999)                         | 236 (± 99999)                           |
| CTau C5D1                                           | 99999 (± 99999)                        | 99999 (± 99999)                        | 99999 (± 99999)                         | 99999 (± 99999)                         |

| End point values                                    | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination |
|-----------------------------------------------------|---------------------------------------------|---------------------------------------------------|--------------------------------------------------|---------------------------------------------------------|
| Subject group type                                  | Reporting group                             | Reporting group                                   | Reporting group                                  | Reporting group                                         |
| Number of subjects analysed                         | 11                                          | 12                                                | 11                                               | 8                                                       |
| Units: ng/mL                                        |                                             |                                                   |                                                  |                                                         |
| geometric mean (geometric coefficient of variation) |                                             |                                                   |                                                  |                                                         |
| Cmax Cycle 1 Day 1                                  | 2735 (± 31)                                 | 454 (± 27)                                        | 1322 (± 40)                                      | 1729 (± 39)                                             |
| Cmax C3D1                                           | 2919 (± 48)                                 | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |
| Cmax Cycle 4 Day 1                                  | 99999 (± 99999)                             | 570 (± 9)                                         | 1706 (± 21)                                      | 1436 (± 99999)                                          |
| Cmax C5D1                                           | 99999 (± 99999)                             | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |
| Ctau Cycle 1 Day 1                                  | 52.6 (± 181)                                | 45.8 (± 322)                                      | 143 (± 51)                                       | 159 (± 58)                                              |
| Ctau C3D1                                           | 149 (± 24)                                  | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |
| Ctau Cycle 4 Day 1                                  | 99999 (± 99999)                             | 170 (± 11)                                        | 115 (± 310)                                      | 107 (± 99999)                                           |
| CTau C5D1                                           | 99999 (± 99999)                             | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |

| <b>End point values</b>                             | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination | Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W |
|-----------------------------------------------------|--------------------------------------------------------|---------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------|
| Subject group type                                  | Reporting group                                        | Reporting group                                   | Reporting group                                        | Reporting group                                         |
| Number of subjects analysed                         | 13                                                     | 9                                                 | 10                                                     | 56                                                      |
| Units: ng/mL                                        |                                                        |                                                   |                                                        |                                                         |
| geometric mean (geometric coefficient of variation) |                                                        |                                                   |                                                        |                                                         |
| Cmax Cycle 1 Day 1                                  | 1397 (± 27)                                            | 2105 (± 26)                                       | 3146 (± 38)                                            | 2274 (± 49)                                             |
| Cmax C3D1                                           | 1894 (± 33)                                            | 1817 (± 32)                                       | 2771 (± 28)                                            | 99999 (± 99999)                                         |
| Cmax Cycle 4 Day 1                                  | 99999 (± 99999)                                        | 99999 (± 99999)                                   | 99999 (± 99999)                                        | 99999 (± 99999)                                         |
| Cmax C5D1                                           | 99999 (± 99999)                                        | 99999 (± 99999)                                   | 99999 (± 99999)                                        | 2022 (± 50)                                             |
| Ctau Cycle 1 Day 1                                  | 20.2 (± 206)                                           | 99999 (± 99999)                                   | 58.7 (± 190)                                           | 57.9 (± 300)                                            |
| Ctau C3D1                                           | 94.4 (± 7)                                             | 99999 (± 99999)                                   | 152 (± 45)                                             | 99999 (± 99999)                                         |
| Ctau Cycle 4 Day 1                                  | 99999 (± 99999)                                        | 99999 (± 99999)                                   | 99999 (± 99999)                                        | 99999 (± 99999)                                         |
| CTau C5D1                                           | 99999 (± 99999)                                        | 99999 (± 99999)                                   | 99999 (± 99999)                                        | 100 (± 83)                                              |

| <b>End point values</b>                             | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W | Part 2B: Cohort 1 (Advanced or Intermediate HCC) | Part 2B: Cohort 2 (Metastatic CRPC) | Part 2B: Cohort 3 (Unresectable TNBC) |
|-----------------------------------------------------|--------------------------------------------------------|--------------------------------------------------|-------------------------------------|---------------------------------------|
| Subject group type                                  | Reporting group                                        | Reporting group                                  | Reporting group                     | Reporting group                       |
| Number of subjects analysed                         | 33                                                     | 5                                                | 39                                  | 38                                    |
| Units: ng/mL                                        |                                                        |                                                  |                                     |                                       |
| geometric mean (geometric coefficient of variation) |                                                        |                                                  |                                     |                                       |
| Cmax Cycle 1 Day 1                                  | 1114 (± 34)                                            | 1752 (± 40)                                      | 2050 (± 27)                         | 2404 (± 41)                           |
| Cmax C3D1                                           | 99999 (± 99999)                                        | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |
| Cmax Cycle 4 Day 1                                  | 930 (± 38)                                             | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |
| Cmax C5D1                                           | 99999 (± 99999)                                        | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |
| Ctau Cycle 1 Day 1                                  | 153 (± 34)                                             | 82.3 (± 61)                                      | 79.3 (± 98)                         | 66.2 (± 153)                          |
| Ctau C3D1                                           | 99999 (± 99999)                                        | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |
| Ctau Cycle 4 Day 1                                  | 151 (± 53)                                             | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |
| CTau C5D1                                           | 99999 (± 99999)                                        | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |

## Statistical analyses

No statistical analyses for this end point

### Secondary: AUC(0-T) and AUC(TAU) of BMS-986249 - Part 1 A and B, Part 2 A Arms C and F, Part 2 B

|                 |                                                                                                       |
|-----------------|-------------------------------------------------------------------------------------------------------|
| End point title | AUC(0-T) and AUC(TAU) of BMS-986249 - Part 1 A and B, Part 2 A Arms C and F, Part 2 B <sup>[38]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------|

End point description:

AUC(0-T): The total amount of BMS-986249 in the blood from the time it is given until a specific time point.

AUC(TAU): The total amount of BMS-986249 in the blood over one dosing interval

Here "99999" = NA

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

On Cycle 1 Day 1, Cycle 3 Day 1, Cycle 4 Day 1, Cycle 5 Day 1 (each cycle=28 days)

Notes:

[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

| End point values                                    | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy | Part 1A: BMS-986249 2400 mg Monotherapy |
|-----------------------------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|-----------------------------------------|
| Subject group type                                  | Reporting group                        | Reporting group                        | Reporting group                         | Reporting group                         |
| Number of subjects analysed                         | 5                                      | 11                                     | 10                                      | 1                                       |
| Units: ng*h/mL                                      |                                        |                                        |                                         |                                         |
| geometric mean (geometric coefficient of variation) |                                        |                                        |                                         |                                         |
| AUC (0-T) Cycle 1 Day 1                             | 77826 (± 48)                           | 294432 (± 39)                          | 745654 (± 40)                           | 991294 (± 99999)                        |
| AUC (Tau) Cycle 1 Day 1                             | 67094 (± 53)                           | 288621 (± 37)                          | 629431 (± 55)                           | 999415 (± 99999)                        |
| AUC (0-T) Cycle 4 Day 1                             | 432 (± 55)                             | 284353 (± 45)                          | 99999 (± 99999)                         | 687899 (± 99999)                        |
| AUC (Tau) Cycle 4 Day 1                             | 51.6 (± 255)                           | 147763 (± 25)                          | 114154 (± 99999)                        | 536764 (± 99999)                        |
| AUC (0-T) C3D1                                      | 99999 (± 99999)                        | 99999 (± 99999)                        | 99999 (± 99999)                         | 99999 (± 99999)                         |
| AUC (Tau) C3D1                                      | 99999 (± 99999)                        | 99999 (± 99999)                        | 99999 (± 99999)                         | 99999 (± 99999)                         |
| AUC (0-T) C5D1                                      | 99999 (± 99999)                        | 99999 (± 99999)                        | 99999 (± 99999)                         | 99999 (± 99999)                         |
| AUC (Tau) C5D1                                      | 99999 (± 99999)                        | 99999 (± 99999)                        | 99999 (± 99999)                         | 99999 (± 99999)                         |

| End point values                                    | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination |
|-----------------------------------------------------|---------------------------------------------|---------------------------------------------------|--------------------------------------------------|---------------------------------------------------------|
| Subject group type                                  | Reporting group                             | Reporting group                                   | Reporting group                                  | Reporting group                                         |
| Number of subjects analysed                         | 11                                          | 12                                                | 11                                               | 8                                                       |
| Units: ng*h/mL                                      |                                             |                                                   |                                                  |                                                         |
| geometric mean (geometric coefficient of variation) |                                             |                                                   |                                                  |                                                         |
| AUC (0-T) Cycle 1 Day 1                             | 671019 (± 48)                               | 96709 (± 49)                                      | 292555 (± 32)                                    | 378115 (± 31)                                           |
| AUC (Tau) Cycle 1 Day 1                             | 484593 (± 74)                               | 88780 (± 61)                                      | 282516 (± 32)                                    | 326037 (± 40)                                           |
| AUC (0-T) Cycle 4 Day 1                             | 99999 (± 99999)                             | 181278 (± 9)                                      | 338096 (± 49)                                    | 255093 (± 99999)                                        |
| AUC (Tau) Cycle 4 Day 1                             | 99999 (± 99999)                             | 139951 (± 71)                                     | 223315 (± 64)                                    | 255093 (± 99999)                                        |
| AUC (0-T) C3D1                                      | 1121470 (± 53)                              | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |
| AUC (Tau) C3D1                                      | 1121470 (± 53)                              | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |
| AUC (0-T) C5D1                                      | 99999 (± 99999)                             | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |
| AUC (Tau) C5D1                                      | 99999 (± 99999)                             | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |

| End point values                                    | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination | Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W |
|-----------------------------------------------------|--------------------------------------------------------|---------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------|
| Subject group type                                  | Reporting group                                        | Reporting group                                   | Reporting group                                        | Reporting group                                         |
| Number of subjects analysed                         | 13                                                     | 9                                                 | 10                                                     | 56                                                      |
| Units: ng*h/mL                                      |                                                        |                                                   |                                                        |                                                         |
| geometric mean (geometric coefficient of variation) |                                                        |                                                   |                                                        |                                                         |
| AUC (0-T) Cycle 1 Day 1                             | 325275 (± 35)                                          | 521156 (± 36)                                     | 688556 (± 29)                                          | 612513 (± 44)                                           |
| AUC (Tau) Cycle 1 Day 1                             | 259533 (± 35)                                          | 458972 (± 41)                                     | 532540 (± 43)                                          | 464205 (± 81)                                           |
| AUC (0-T) Cycle 4 Day 1                             | 99999 (± 99999)                                        | 99999 (± 99999)                                   | 99999 (± 99999)                                        | 99999 (± 99999)                                         |
| AUC (Tau) Cycle 4 Day 1                             | 99999 (± 99999)                                        | 99999 (± 99999)                                   | 99999 (± 99999)                                        | 99999 (± 99999)                                         |
| AUC (0-T) C3D1                                      | 611831 (± 19)                                          | 780896 (± 45)                                     | 972214 (± 28)                                          | 99999 (± 99999)                                         |
| AUC (Tau) C3D1                                      | 611831 (± 19)                                          | 780896 (± 45)                                     | 937806 (± 25)                                          | 99999 (± 99999)                                         |
| AUC (0-T) C5D1                                      | 99999 (± 99999)                                        | 99999 (± 99999)                                   | 99999 (± 99999)                                        | 675816 (± 33)                                           |
| AUC (Tau) C5D1                                      | 99999 (± 99999)                                        | 99999 (± 99999)                                   | 99999 (± 99999)                                        | 564180 (± 52)                                           |

| End point values | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg | Part 2B: Cohort 1 (Advanced or Intermediate HCC) | Part 2B: Cohort 2 (Metastatic CRPC) | Part 2B: Cohort 3 (Unresectable TNBC) |
|------------------|----------------------------------------------------|--------------------------------------------------|-------------------------------------|---------------------------------------|
|------------------|----------------------------------------------------|--------------------------------------------------|-------------------------------------|---------------------------------------|

|                                                     | Q4W             |                 |                 |                 |
|-----------------------------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type                                  | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed                         | 33              | 5               | 39              | 38              |
| Units: ng*h/mL                                      |                 |                 |                 |                 |
| geometric mean (geometric coefficient of variation) |                 |                 |                 |                 |
| AUC (0-T) Cycle 1 Day 1                             | 255384 (± 23)   | 653770 (± 7)    | 638435 (± 24)   | 696815 (± 34)   |
| AUC (Tau) Cycle 1 Day 1                             | 231346 (± 48)   | 407104 (± 56)   | 438370 (± 70)   | 554691 (± 52)   |
| AUC (0-T) Cycle 4 Day 1                             | 260319 (± 35)   | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AUC (Tau) Cycle 4 Day 1                             | 229430 (± 37)   | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AUC (0-T) C3D1                                      | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AUC (Tau) C3D1                                      | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AUC (0-T) C5D1                                      | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AUC (Tau) C5D1                                      | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Accumulation Index for Cmax (AI\_Cmax) and Accumulation Index for AUC (AI\_AUC) of BMS-986249 - Part 1 A and B, Part 2 A Arms C, D and F, Part 2 B

|                 |                                                                                                                                                                  |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Accumulation Index for Cmax (AI_Cmax) and Accumulation Index for AUC (AI_AUC) of BMS-986249 - Part 1 A and B, Part 2 A Arms C, D and F, Part 2 B <sup>[39]</sup> |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

AI\_Cmax: How much the highest concentration of BMS-986249 increases after multiple doses compared to a single dose.

AI\_AUC: How much the total exposure to BMS-986249 increases after multiple doses compared to a single dose.

Here "99999" = NA

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

On Cycle 1 Day 1, Cycle 3 Day 1, Cycle 4 Day 1, Cycle 5 Day 1 (each cycle=28 days)

Notes:

[39] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: as per protocol, these are the defined arms for this endpoint

| End point values                                    | Part 1A: BMS-986249 240 mg Monotherapy | Part 1A: BMS-986249 800 mg Monotherapy | Part 1A: BMS-986249 1600 mg Monotherapy | Part 1A: BMS-986249 2400 mg Monotherapy |
|-----------------------------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|-----------------------------------------|
| Subject group type                                  | Reporting group                        | Reporting group                        | Reporting group                         | Reporting group                         |
| Number of subjects analysed                         | 5                                      | 11                                     | 10                                      | 1                                       |
| Units: ratio                                        |                                        |                                        |                                         |                                         |
| geometric mean (geometric coefficient of variation) |                                        |                                        |                                         |                                         |

|                        |                 |                 |                 |                 |
|------------------------|-----------------|-----------------|-----------------|-----------------|
| AI (AUC) Cycle 1 Day 1 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AI Cmax Cycle 1 Day 1  | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AI (AUC) Cycle 4 Day 1 | 1.29 (± 11)     | 1.07 (± 29)     | 99999 (± 99999) | 0.694 (± 99999) |
| AI Cmax Cycle 4 Day 1  | 1.02 (± 14)     | 324 (± 99999)   | 1.32 (± 99999)  | 0.788 (± 99999) |
| AI (AUC) C3D1          | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AI Cmax C3D1           | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AI (AUC) C5D1          | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AI Cmax C5D1           | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |

| End point values                                    | Part 1A: BMS-986249 1600 mg Q8W Monotherapy | Part 1B: BMS-986249 240 mg Q4W + Nivo Combination | Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination | Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination |
|-----------------------------------------------------|---------------------------------------------|---------------------------------------------------|--------------------------------------------------|---------------------------------------------------------|
| Subject group type                                  | Reporting group                             | Reporting group                                   | Reporting group                                  | Reporting group                                         |
| Number of subjects analysed                         | 11                                          | 12                                                | 11                                               | 8                                                       |
| Units: ratio                                        |                                             |                                                   |                                                  |                                                         |
| geometric mean (geometric coefficient of variation) |                                             |                                                   |                                                  |                                                         |
| AI (AUC) Cycle 1 Day 1                              | 99999 (± 99999)                             | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |
| AI Cmax Cycle 1 Day 1                               | 99999 (± 99999)                             | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |
| AI (AUC) Cycle 4 Day 1                              | 99999 (± 99999)                             | 1.54 (± 1)                                        | 1.23 (± 16)                                      | 1.29 (± 99999)                                          |
| AI Cmax Cycle 4 Day 1                               | 99999 (± 99999)                             | 1.28 (± 10)                                       | 1.25 (± 17)                                      | 1.62 (± 99999)                                          |
| AI (AUC) C3D1                                       | 1.35 (± 7)                                  | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |
| AI Cmax C3D1                                        | 1.17 (± 3)                                  | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |
| AI (AUC) C5D1                                       | 99999 (± 99999)                             | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |
| AI Cmax C5D1                                        | 99999 (± 99999)                             | 99999 (± 99999)                                   | 99999 (± 99999)                                  | 99999 (± 99999)                                         |

| End point values                                    | Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination | Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination | Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination | Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W |
|-----------------------------------------------------|--------------------------------------------------------|---------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------|
| Subject group type                                  | Reporting group                                        | Reporting group                                   | Reporting group                                        | Reporting group                                         |
| Number of subjects analysed                         | 13                                                     | 9                                                 | 10                                                     | 56                                                      |
| Units: ratio                                        |                                                        |                                                   |                                                        |                                                         |
| geometric mean (geometric coefficient of variation) |                                                        |                                                   |                                                        |                                                         |

|                        |                 |                 |                 |                 |
|------------------------|-----------------|-----------------|-----------------|-----------------|
| AI (AUC) Cycle 1 Day 1 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AI Cmax Cycle 1 Day 1  | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AI (AUC) Cycle 4 Day 1 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AI Cmax Cycle 4 Day 1  | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| AI (AUC) C3D1          | 1.82 (± 43)     | 1.3 (± 17)      | 1.46 (± 11)     | 99999 (± 99999) |
| AI Cmax C3D1           | 1.58 (± 85)     | 0.918 (± 16)    | 0.978 (± 14)    | 99999 (± 99999) |
| AI (AUC) C5D1          | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 1.13 (± 18)     |
| AI Cmax C5D1           | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 1.11 (± 53)     |

| End point values                                    | Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W | Part 2B: Cohort 1 (Advanced or Intermediate HCC) | Part 2B: Cohort 2 (Metastatic CRPC) | Part 2B: Cohort 3 (Unresectable TNBC) |
|-----------------------------------------------------|--------------------------------------------------------|--------------------------------------------------|-------------------------------------|---------------------------------------|
| Subject group type                                  | Reporting group                                        | Reporting group                                  | Reporting group                     | Reporting group                       |
| Number of subjects analysed                         | 33                                                     | 5                                                | 39                                  | 38                                    |
| Units: ratio                                        |                                                        |                                                  |                                     |                                       |
| geometric mean (geometric coefficient of variation) |                                                        |                                                  |                                     |                                       |
| AI (AUC) Cycle 1 Day 1                              | 99999 (± 99999)                                        | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |
| AI Cmax Cycle 1 Day 1                               | 99999 (± 99999)                                        | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |
| AI (AUC) Cycle 4 Day 1                              | 0.971 (± 24)                                           | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |
| AI Cmax Cycle 4 Day 1                               | 0.899 (± 64)                                           | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |
| AI (AUC) C3D1                                       | 99999 (± 99999)                                        | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |
| AI Cmax C3D1                                        | 99999 (± 99999)                                        | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |
| AI (AUC) C5D1                                       | 99999 (± 99999)                                        | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |
| AI Cmax C5D1                                        | 99999 (± 99999)                                        | 99999 (± 99999)                                  | 99999 (± 99999)                     | 99999 (± 99999)                       |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants with Shifts from Baseline in Laboratory Test results – Part 2A (Arms C and F) and 2B

|                        |                                                                                                             |
|------------------------|-------------------------------------------------------------------------------------------------------------|
| End point title        | Number of Participants with Shifts from Baseline in Laboratory Test results – Part 2A (Arms C and F) and 2B |
| End point description: |                                                                                                             |

|                                                                                                |           |
|------------------------------------------------------------------------------------------------|-----------|
| End point type                                                                                 | Secondary |
| End point timeframe:                                                                           |           |
| From first dose until 100 days after last dose of study therapy (up to approximately 38 weeks) |           |

| End point values                               | Part 2A Arm C:<br>BMS-986249<br>1200 mg Q6W<br>+ Nivo 480 mg<br>Q4W | Part 2A Arm D:<br>Ipilimumab 3<br>mg/kg Q3W +<br>Nivo 1 mg/kg<br>Q3W | Part 2A Arm F:<br>BMS-986249<br>1200 mg Q6W<br>+ Nivo 480 mg<br>Q4W | Part 2B: Cohort<br>1 (Advanced or<br>Intermediate<br>HCC): |
|------------------------------------------------|---------------------------------------------------------------------|----------------------------------------------------------------------|---------------------------------------------------------------------|------------------------------------------------------------|
| Subject group type                             | Subject analysis set                                                | Subject analysis set                                                 | Subject analysis set                                                | Subject analysis set                                       |
| Number of subjects analysed                    | 57                                                                  | 58                                                                   | 36                                                                  | 5                                                          |
| Units: Participants                            |                                                                     |                                                                      |                                                                     |                                                            |
| HEMOGLOBIN                                     | 42                                                                  | 43                                                                   | 25                                                                  | 3                                                          |
| PLATELET COUNT                                 | 13                                                                  | 10                                                                   | 7                                                                   | 2                                                          |
| LEUKOCYTES, LOCAL LAB                          | 12                                                                  | 10                                                                   | 6                                                                   | 0                                                          |
| ABSOLUTE NEUTROPHIL COUNT DRV                  | 7                                                                   | 8                                                                    | 6                                                                   | 0                                                          |
| LYMPHOCYTES (ABSOLUTE)                         | 9                                                                   | 19                                                                   | 10                                                                  | 0                                                          |
| LYMPHOCYTES (ABSOLUTE), LOCAL LAB              | 23                                                                  | 12                                                                   | 10                                                                  | 2                                                          |
| CREATININE, LOCAL LAB                          | 20                                                                  | 17                                                                   | 10                                                                  | 3                                                          |
| ALKALINE PHOSPHATASE (ALP) LOCAL<br>LAB        | 24                                                                  | 30                                                                   | 19                                                                  | 3                                                          |
| ALANINE AMINOTRANSFERASE (ALT),<br>LOCAL LAB   | 38                                                                  | 40                                                                   | 23                                                                  | 4                                                          |
| ASPARTATE AMINOTRANSFERASE<br>(AST), LOCAL LAB | 27                                                                  | 40                                                                   | 22                                                                  | 3                                                          |
| BILIRUBIN, TOTAL, LOCAL LAB                    | 12                                                                  | 18                                                                   | 7                                                                   | 3                                                          |

| End point values                               | Part 2B Cohort<br>2 (Metastatic<br>CRPC) | Part 2B: Cohort<br>3<br>(Unresectable<br>TNBC) |  |  |
|------------------------------------------------|------------------------------------------|------------------------------------------------|--|--|
| Subject group type                             | Subject analysis set                     | Subject analysis set                           |  |  |
| Number of subjects analysed                    | 41                                       | 45                                             |  |  |
| Units: Participants                            |                                          |                                                |  |  |
| HEMOGLOBIN                                     | 32                                       | 33                                             |  |  |
| PLATELET COUNT                                 | 15                                       | 12                                             |  |  |
| LEUKOCYTES, LOCAL LAB                          | 9                                        | 14                                             |  |  |
| ABSOLUTE NEUTROPHIL COUNT DRV                  | 9                                        | 10                                             |  |  |
| LYMPHOCYTES (ABSOLUTE)                         | 11                                       | 11                                             |  |  |
| LYMPHOCYTES (ABSOLUTE), LOCAL LAB              | 9                                        | 17                                             |  |  |
| CREATININE, LOCAL LAB                          | 14                                       | 5                                              |  |  |
| ALKALINE PHOSPHATASE (ALP) LOCAL<br>LAB        | 17                                       | 25                                             |  |  |
| ALANINE AMINOTRANSFERASE (ALT),<br>LOCAL LAB   | 18                                       | 27                                             |  |  |
| ASPARTATE AMINOTRANSFERASE<br>(AST), LOCAL LAB | 19                                       | 31                                             |  |  |
| BILIRUBIN, TOTAL, LOCAL LAB                    | 12                                       | 5                                              |  |  |

## **Statistical analyses**

---

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse Events and Serious Adverse Events: (From first dose to last dose + 100 days): Approximately 38 weeks

All-Cause mortality (From randomization to end of study): Approximately 83 Months

Adverse event reporting additional description:

The number at Risk for All-Cause Mortality represents all Randomized Participants. The number at Risk for Serious Adverse Events and Other (Not Including Serious) Adverse Events represents all participants that received at least 1 dose of study medication

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 27.1 |
|--------------------|------|

### Reporting groups

|                       |                                          |
|-----------------------|------------------------------------------|
| Reporting group title | Part 1A: BMS-986249 Monotherapy 2400 Q4W |
|-----------------------|------------------------------------------|

Reporting group description:

BMS-986249 2400 mg IV Q4W, up to 2 years

|                       |                                          |
|-----------------------|------------------------------------------|
| Reporting group title | Part 1A: BMS-986249 Monotherapy 1600 Q4W |
|-----------------------|------------------------------------------|

Reporting group description:

BMS-986249 1600 mg IV Q4W, up to 2 years

|                       |                                             |
|-----------------------|---------------------------------------------|
| Reporting group title | Part 1A: BMS-986249 Monotherapy BMS 800 Q4W |
|-----------------------|---------------------------------------------|

Reporting group description:

BMS-986249 800 mg IV Q4W, up to 2 years

|                       |                                               |
|-----------------------|-----------------------------------------------|
| Reporting group title | Part 1A: BMS-986249 Monotherapy 240 mg IV Q4W |
|-----------------------|-----------------------------------------------|

Reporting group description:

BMS-986249 240 mg IV Q4W, up to 2 years

|                       |                                          |
|-----------------------|------------------------------------------|
| Reporting group title | Part 1A: BMS-986249 Monotherapy 1600 Q8W |
|-----------------------|------------------------------------------|

Reporting group description:

BMS-986249 1600 mg IV Q8W, up to 2 years

|                       |                                                      |
|-----------------------|------------------------------------------------------|
| Reporting group title | Part 1B: BMS-986249 800mg Q8W+ Nivolumab Combination |
|-----------------------|------------------------------------------------------|

Reporting group description:

BMS-986249 800 mg IV Q8W + Nivolumab 480 mg IV Q8W

|                       |                                                        |
|-----------------------|--------------------------------------------------------|
| Reporting group title | Part 1B: BMS-986249 1200mg Q4W + Nivolumab Combination |
|-----------------------|--------------------------------------------------------|

Reporting group description:

BMS-986249 1200 mg IV Q4W + Nivolumab 480 mg IV Q6W

|                       |                                                       |
|-----------------------|-------------------------------------------------------|
| Reporting group title | Part 1B: BMS-986249 800mg Q4W + Nivolumab Combination |
|-----------------------|-------------------------------------------------------|

Reporting group description:

BMS-986249 800 mg IV Q4W + Nivolumab 480 mg IV Q4W

|                       |                                                       |
|-----------------------|-------------------------------------------------------|
| Reporting group title | Part 1B: BMS-986249 240mg Q4W + Nivolumab Combination |
|-----------------------|-------------------------------------------------------|

Reporting group description:

BMS-986249 240 mg IV Q4W + Nivolumab 480 mg IV Q4W

|                       |                                                       |
|-----------------------|-------------------------------------------------------|
| Reporting group title | Part 1B: BMS-986249 1200mg Q8W+ Nivolumab Combination |
|-----------------------|-------------------------------------------------------|

Reporting group description:

BMS-986249 1200 mg IV Q8W + Nivolumab 480 mg IV Q8W

|                       |                                                       |
|-----------------------|-------------------------------------------------------|
| Reporting group title | Part 1B: BMS-986249 1600mg Q8W+ Nivolumab Combination |
|-----------------------|-------------------------------------------------------|

Reporting group description:

BMS-986249 1600 mg IV Q8W + Nivolumab 480 mg IV Q4W

|                       |                                                |
|-----------------------|------------------------------------------------|
| Reporting group title | Part 2A: Melanoma Arms BMS-986249 240mg IV Q3W |
|-----------------------|------------------------------------------------|

Reporting group description:

BMS-986249 240 mg IV Q3W + Nivolumab 360 mg IV Q3W (14 doses), then Nivolumab 480 mg IV Q4W (maintenance)

|                       |                                                |
|-----------------------|------------------------------------------------|
| Reporting group title | Part 2A: Melanoma Arms BMS-986249 800mg IV Q3W |
|-----------------------|------------------------------------------------|

Reporting group description:

BMS-986249 800 mg IV Q3W + Nivolumab 480 mg IV Q3W (14 doses), then Nivolumab 480 mg IV Q4W (maintenance)

|                       |                                                 |
|-----------------------|-------------------------------------------------|
| Reporting group title | Part 2A: Melanoma Arms BMS-986249 1200mg IV Q3W |
|-----------------------|-------------------------------------------------|

Reporting group description:

BMS-986249 1200 mg IV Q3W + Nivolumab 480 mg IV Q3W (14 doses), then Nivolumab 480 mg IV Q4W (maintenance)

|                       |                                                 |
|-----------------------|-------------------------------------------------|
| Reporting group title | Part 2A: Melanoma Arms Ipilimumab 3mg/kg IV Q3W |
|-----------------------|-------------------------------------------------|

Reporting group description:

Ipilimumab 3 mg/kg IV Q3W + Nivolumab 1 mg/kg IV Q3W (4 doses), then Nivolumab 480 mg IV Q4W (maintenance), up to 2 years

|                       |                                       |
|-----------------------|---------------------------------------|
| Reporting group title | Part 2A: Melanoma Arms Nivolumab Mono |
|-----------------------|---------------------------------------|

Reporting group description:

Nivolumab 480 mg IV Q4W Monotherapy

|                       |                                                |
|-----------------------|------------------------------------------------|
| Reporting group title | Part 2A: Melanoma Arms BMS-986249 600mg IV Q8W |
|-----------------------|------------------------------------------------|

Reporting group description:

BMS-986249 600 mg IV Q8W + Nivolumab 480 mg IV Q8W (Melanoma-specific combination)

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | Part 2B: Cohort 1 (HCC) |
|-----------------------|-------------------------|

Reporting group description:

BMS-986249 1200 mg IV Q8W + Nivolumab 480 mg IV Q8W

|                       |                                     |
|-----------------------|-------------------------------------|
| Reporting group title | Part 2B: Cohort 2 (Metastatic CRPC) |
|-----------------------|-------------------------------------|

Reporting group description:

BMS-986249 1200 mg IV Q8W + Nivolumab 480 mg IV Q8W

|                       |                                       |
|-----------------------|---------------------------------------|
| Reporting group title | Part 2B: Cohort 3 (Unresectable TNBC) |
|-----------------------|---------------------------------------|

Reporting group description:

BMS-986249 1200 mg IV Q8W + Nivolumab 480 mg IV Q8W

| Serious adverse events                                              | Part 1A: BMS-986249 Monotherapy 2400 Q4W | Part 1A: BMS-986249 Monotherapy 1600 Q4W | Part 1A: BMS-986249 Monotherapy BMS 800 Q4W |
|---------------------------------------------------------------------|------------------------------------------|------------------------------------------|---------------------------------------------|
| Total subjects affected by serious adverse events                   |                                          |                                          |                                             |
| subjects affected / exposed                                         | 1 / 1 (100.00%)                          | 8 / 10 (80.00%)                          | 8 / 11 (72.73%)                             |
| number of deaths (all causes)                                       | 1                                        | 7                                        | 10                                          |
| number of deaths resulting from adverse events                      | 1                                        | 2                                        | 6                                           |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                          |                                          |                                             |
| Malignant neoplasm progression                                      |                                          |                                          |                                             |
| subjects affected / exposed                                         | 1 / 1 (100.00%)                          | 1 / 10 (10.00%)                          | 6 / 11 (54.55%)                             |
| occurrences causally related to treatment / all                     | 0 / 1                                    | 0 / 1                                    | 0 / 6                                       |
| deaths causally related to treatment / all                          | 0 / 1                                    | 0 / 1                                    | 0 / 6                                       |
| Metastases to bone                                                  |                                          |                                          |                                             |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Metastases to spine                             |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Metastatic malignant melanoma                   |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Neoplasm malignant                              |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Neoplasm progression                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tumour haemorrhage                              |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tumour pain                                     |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Vascular disorders                              |               |                |                |
| Arterial haemorrhage                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Bleeding varicose vein                          |               |                |                |

|                                                      |               |                 |                |
|------------------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0           | 0 / 0          |
| Deep vein thrombosis                                 |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0           | 0 / 0          |
| Embolism                                             |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0           | 0 / 0          |
| Haemorrhage                                          |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0           | 0 / 0          |
| Hypotension                                          |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0           | 0 / 0          |
| Vasculitis                                           |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0           | 0 / 0          |
| Peripheral embolism                                  |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0           | 0 / 0          |
| General disorders and administration site conditions |               |                 |                |
| Fatigue                                              |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0           | 0 / 0          |
| Oedema peripheral                                    |               |                 |                |

|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Pain                                            |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Performance status decreased                    |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Pyrexia                                         |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Sudden death                                    |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Systemic inflammatory response syndrome         |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |               |                 |                |
| Acute respiratory failure                       |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Atelectasis                                     |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Dyspnoea                                        |               |                 |                |

|                                                 |               |                 |                 |
|-------------------------------------------------|---------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0           |
| Hypoxia                                         |               |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0           |
| Pleural effusion                                |               |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0           |
| Pleuritic pain                                  |               |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0           |
| Pneumothorax                                    |               |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0           |
| Pneumonitis                                     |               |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0           |
| Pulmonary embolism                              |               |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 2 / 11 (18.18%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 2           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0           |
| Respiratory distress                            |               |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0           |
| Respiratory failure                             |               |                 |                 |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Psychiatric disorders                           |               |                |                |
| Confusional state                               |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Investigations                                  |               |                |                |
| Alanine aminotransferase increased              |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Aspartate aminotransferase increased            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Blood alkaline phosphatase increased            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Blood bilirubin increased                       |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Blood creatinine increased                      |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Liver function test increased                   |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Transaminases increased                         |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Troponin I increased                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Injury, poisoning and procedural complications  |               |                |                |
| Fall                                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hip fracture                                    |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Humerus fracture                                |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Subdural haematoma                              |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cardiac disorders                               |               |                |                |
| Acute myocardial infarction                     |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Arrhythmia                                      |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Atrial fibrillation                             |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cardiac tamponade                               |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cardio-respiratory arrest                       |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated myocarditis                     |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myocardial infarction                           |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myocardial ischaemia                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myocarditis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pericardial effusion                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Supraventricular tachycardia                    |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nervous system disorders                        |               |                |                |
| Brain oedema                                    |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebral haemorrhage                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebral infarction                             |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebrovascular accident                        |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebral ischaemia                              |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Facial paresis                                  |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemorrhage intracranial                        |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Headache                                        |               |                |                |

|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Seizure                                         |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Paraparesis                                     |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Somnolence                                      |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Syncope                                         |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Transient ischaemic attack                      |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Tremor                                          |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Blood and lymphatic system disorders            |               |                 |                |
| Anaemia                                         |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Aplasia pure red cell                           |               |                 |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Febrile neutropenia                             |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemolysis                                      |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemolytic anaemia                              |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Heparin-induced thrombocytopenia                |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pancytopenia                                    |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Ear and labyrinth disorders                     |               |                |                |
| Vertigo                                         |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Eye disorders                                   |               |                |                |
| Uveitis                                         |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                      |               |                |                |

|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| Abdominal pain                                  |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Ascites                                         |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Autoimmune colitis                              |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Colitis                                         |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 2 / 10 (20.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 2           | 2 / 2          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Colitis ulcerative                              |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Diarrhoea                                       |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 2 / 10 (20.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 2 / 2           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Duodenal ulcer                                  |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Dysphagia                                       |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Gastric haemorrhage                             |               |                 |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastrointestinal haemorrhage                    |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated enterocolitis                   |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Intestinal obstruction                          |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Intestinal perforation                          |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Lower gastrointestinal haemorrhage              |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nausea                                          |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Odynophagia                                     |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Oesophagitis                                    |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pancreatitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pancreatitis acute                              |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Portal hypertensive gastropathy                 |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Small intestinal obstruction                    |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Small intestinal perforation                    |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Upper gastrointestinal haemorrhage              |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Vomiting                                        |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hepatobiliary disorders                         |               |                |                |
| Cholecystitis                                   |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cholecystitis acute                             |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hepatitis                                       |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hepatotoxicity                                  |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypertransaminasaemia                           |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated hepatic disorder                |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated hepatitis                       |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Jaundice cholestatic                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders          |               |                |                |
| Acute generalised exanthematous pustulosis      |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Rash                                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Rash maculo-papular                             |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Renal and urinary disorders                     |               |                |                |
| Acute kidney injury                             |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated nephritis                       |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nephrolithiasis                                 |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Renal failure                                   |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Urinary tract obstruction                       |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tubulointerstitial nephritis                    |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Endocrine disorders                             |               |                |                |
| Adrenal insufficiency                           |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hyperthyroidism                                 |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypophysitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypopituitarism                                 |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated hypophysitis                    |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Thyroiditis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Musculoskeletal and connective tissue disorders |               |                |                |
| Back pain                                       |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Haematoma muscle                                |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Musculoskeletal chest pain                      |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myositis                                        |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pathological fracture                           |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Spinal stenosis                                 |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Infections and infestations                     |               |                |                |
| Bacteraemia                                     |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| COVID-19                                        |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| COVID-19 pneumonia                              |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Clostridium difficile colitis                   |               |                |                |

|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Device related infection                        |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Encephalitis                                    |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Enterocolitis infectious                        |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Gastroenteritis                                 |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Gastrointestinal infection                      |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Klebsiella urinary tract infection              |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Listeriosis                                     |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Pneumonia                                       |               |                 |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumonia influenzal                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Post procedural infection                       |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Postoperative wound infection                   |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pulmonary sepsis                                |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pyelonephritis                                  |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pyelonephritis acute                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Respiratory tract infection                     |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Sepsis                                          |               |                |                |

|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Septic shock                                    |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 1           | 0 / 0          |
| Staphylococcal bacteraemia                      |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Upper respiratory tract infection               |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Urinary tract infection                         |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Urosepsis                                       |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Viral infection                                 |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Metabolism and nutrition disorders              |               |                 |                |
| Diabetes mellitus                               |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Diabetic ketoacidosis                           |               |                 |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Hypercalcaemia</b>                           |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Hyperglycaemia</b>                           |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Hypocalcaemia</b>                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Hypoglycaemia</b>                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Hyponatraemia</b>                            |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Malnutrition</b>                             |               |                |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

| <b>Serious adverse events</b>                     | Part 1A: BMS-986249<br>Monotherapy 240 mg IV Q4W | Part 1A: BMS-986249<br>Monotherapy 1600 Q8W | Part 1B: BMS-986249 800mg Q8W+ Nivolumab Combination |
|---------------------------------------------------|--------------------------------------------------|---------------------------------------------|------------------------------------------------------|
| Total subjects affected by serious adverse events |                                                  |                                             |                                                      |
| subjects affected / exposed                       | 4 / 6 (66.67%)                                   | 7 / 11 (63.64%)                             | 10 / 13 (76.92%)                                     |
| number of deaths (all causes)                     | 4                                                | 6                                           | 8                                                    |
| number of deaths resulting from adverse events    | 2                                                | 2                                           | 5                                                    |

|                                                                     |                |                |                 |
|---------------------------------------------------------------------|----------------|----------------|-----------------|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                |                |                 |
| Malignant neoplasm progression                                      |                |                |                 |
| subjects affected / exposed                                         | 3 / 6 (50.00%) | 1 / 11 (9.09%) | 3 / 13 (23.08%) |
| occurrences causally related to treatment / all                     | 0 / 3          | 0 / 1          | 0 / 3           |
| deaths causally related to treatment / all                          | 0 / 2          | 0 / 1          | 0 / 3           |
| Metastases to bone                                                  |                |                |                 |
| subjects affected / exposed                                         | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 1          | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0           |
| Metastases to spine                                                 |                |                |                 |
| subjects affected / exposed                                         | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0           |
| Metastatic malignant melanoma                                       |                |                |                 |
| subjects affected / exposed                                         | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0           |
| Neoplasm malignant                                                  |                |                |                 |
| subjects affected / exposed                                         | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0           |
| Neoplasm progression                                                |                |                |                 |
| subjects affected / exposed                                         | 0 / 6 (0.00%)  | 1 / 11 (9.09%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 1          | 0 / 0           |
| Tumour haemorrhage                                                  |                |                |                 |
| subjects affected / exposed                                         | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0           |
| Tumour pain                                                         |                |                |                 |
| subjects affected / exposed                                         | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0           |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Vascular disorders                              |               |                |                |
| Arterial haemorrhage                            |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Bleeding varicose vein                          |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Deep vein thrombosis                            |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Embolism                                        |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemorrhage                                     |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypotension                                     |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Vasculitis                                      |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Peripheral embolism                             |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| General disorders and administration            |               |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| site conditions                                 |                |                |                |
| Fatigue                                         |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Oedema peripheral                               |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pain                                            |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Performance status decreased                    |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pyrexia                                         |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Sudden death                                    |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Systemic inflammatory response syndrome         |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |                |                |                |
| Acute respiratory failure                       |                |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Atelectasis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Dyspnoea                                        |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypoxia                                         |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pleural effusion                                |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pleuritic pain                                  |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumothorax                                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumonitis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pulmonary embolism                              |               |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Respiratory distress                            |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Respiratory failure                             |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| Psychiatric disorders                           |                |                |                |
| Confusional state                               |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Investigations                                  |                |                |                |
| Alanine aminotransferase increased              |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Aspartate aminotransferase increased            |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Blood alkaline phosphatase increased            |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Blood bilirubin increased                       |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| Blood creatinine increased                      |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Liver function test increased                   |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Transaminases increased                         |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Troponin I increased                            |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Injury, poisoning and procedural complications  |                |                |                |
| Fall                                            |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hip fracture                                    |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Humerus fracture                                |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Subdural haematoma                              |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Cardiac disorders                               |               |                |                |
| Acute myocardial infarction                     |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Arrhythmia                                      |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Atrial fibrillation                             |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cardiac tamponade                               |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cardio-respiratory arrest                       |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated myocarditis                     |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myocardial infarction                           |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myocardial ischaemia                            |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myocarditis                                     |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pericardial effusion                            |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Supraventricular tachycardia                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nervous system disorders                        |               |                |                |
| Brain oedema                                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebral haemorrhage                            |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebral infarction                             |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebrovascular accident                        |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebral ischaemia                              |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Facial paresis                                  |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemorrhage intracranial                        |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Headache                                        |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Seizure                                         |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Paraparesis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Somnolence                                      |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Syncope                                         |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Transient ischaemic attack                      |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tremor                                          |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Blood and lymphatic system disorders</b>     |               |                |                |
| <b>Anaemia</b>                                  |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Aplasia pure red cell</b>                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Febrile neutropenia</b>                      |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Haemolysis</b>                               |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Haemolytic anaemia</b>                       |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Heparin-induced thrombocytopenia</b>         |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Pancytopenia</b>                             |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Ear and labyrinth disorders</b>              |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Vertigo                                         |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Eye disorders                                   |               |                |                |
| Uveitis                                         |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                      |               |                |                |
| Abdominal pain                                  |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Ascites                                         |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Autoimmune colitis                              |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Colitis                                         |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Colitis ulcerative                              |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Diarrhoea                                       |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Duodenal ulcer                                  |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Dysphagia                                       |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastric haemorrhage                             |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastrointestinal haemorrhage                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated enterocolitis                   |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Intestinal obstruction                          |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Intestinal perforation                          |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Lower gastrointestinal haemorrhage              |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nausea                                          |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Odynophagia                                     |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Oesophagitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pancreatitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pancreatitis acute                              |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Portal hypertensive gastropathy                 |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Small intestinal obstruction                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 1 / 11 (9.09%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Small intestinal perforation                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 1          |
| Upper gastrointestinal haemorrhage              |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Vomiting                                        |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hepatobiliary disorders                         |               |                |                |
| Cholecystitis                                   |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cholecystitis acute                             |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hepatitis                                       |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hepatotoxicity                                  |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypertransaminasaemia                           |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated hepatic disorder                |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated hepatitis                       |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Jaundice cholestatic                            |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 2          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders          |               |                |                |
| Acute generalised exanthematous pustulosis      |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Rash                                            |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Rash maculo-papular                             |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Renal and urinary disorders                     |               |                |                |
| Acute kidney injury                             |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated nephritis                       |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nephrolithiasis                                 |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Renal failure                                   |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Urinary tract obstruction                       |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tubulointerstitial nephritis                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Endocrine disorders                             |               |                |                |
| Adrenal insufficiency                           |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hyperthyroidism                                 |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypophysitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypopituitarism                                 |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated hypophysitis                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Thyroiditis                                     |               |                |                |

|                                                        |               |                |                |
|--------------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                            | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Musculoskeletal and connective tissue disorders</b> |               |                |                |
| Back pain                                              |               |                |                |
| subjects affected / exposed                            | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| Haematoma muscle                                       |               |                |                |
| subjects affected / exposed                            | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| Musculoskeletal chest pain                             |               |                |                |
| subjects affected / exposed                            | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| Myositis                                               |               |                |                |
| subjects affected / exposed                            | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| Pathological fracture                                  |               |                |                |
| subjects affected / exposed                            | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| Spinal stenosis                                        |               |                |                |
| subjects affected / exposed                            | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Infections and infestations</b>                     |               |                |                |
| Bacteraemia                                            |               |                |                |
| subjects affected / exposed                            | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| COVID-19                                        |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| COVID-19 pneumonia                              |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Clostridium difficile colitis                   |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Device related infection                        |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Encephalitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Enterocolitis infectious                        |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastroenteritis                                 |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastrointestinal infection                      |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Klebsiella urinary tract infection              |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Listeriosis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumonia                                       |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumonia influenzal                            |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Post procedural infection                       |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Postoperative wound infection                   |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pulmonary sepsis                                |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pyelonephritis                                  |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pyelonephritis acute                            |               |                |                |

|                                                 |               |                |                 |
|-------------------------------------------------|---------------|----------------|-----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0           |
| Respiratory tract infection                     |               |                |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0           |
| Sepsis                                          |               |                |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 2 / 13 (15.38%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 2           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0           |
| Septic shock                                    |               |                |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0           |
| Staphylococcal bacteraemia                      |               |                |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0           |
| Upper respiratory tract infection               |               |                |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0           |
| Urinary tract infection                         |               |                |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0           |
| Urosepsis                                       |               |                |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0           |
| Viral infection                                 |               |                |                 |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |               |                |                |
| Diabetes mellitus                               |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Diabetic ketoacidosis                           |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypercalcaemia                                  |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hyperglycaemia                                  |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypocalcaemia                                   |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypoglycaemia                                   |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hyponatraemia                                   |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Malnutrition                                    |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

| <b>Serious adverse events</b>                                       | Part 1B: BMS-986249 1200mg Q4W + Nivolumab Combination | Part 1B: BMS-986249 800mg Q4W + Nivolumab Combination | Part 1B: BMS-986249 240mg Q4W + Nivolumab Combination |
|---------------------------------------------------------------------|--------------------------------------------------------|-------------------------------------------------------|-------------------------------------------------------|
| Total subjects affected by serious adverse events                   |                                                        |                                                       |                                                       |
| subjects affected / exposed                                         | 7 / 9 (77.78%)                                         | 7 / 11 (63.64%)                                       | 8 / 12 (66.67%)                                       |
| number of deaths (all causes)                                       | 7                                                      | 8                                                     | 11                                                    |
| number of deaths resulting from adverse events                      | 5                                                      | 3                                                     | 3                                                     |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                                        |                                                       |                                                       |
| Malignant neoplasm progression                                      |                                                        |                                                       |                                                       |
| subjects affected / exposed                                         | 5 / 9 (55.56%)                                         | 4 / 11 (36.36%)                                       | 3 / 12 (25.00%)                                       |
| occurrences causally related to treatment / all                     | 0 / 5                                                  | 0 / 4                                                 | 0 / 3                                                 |
| deaths causally related to treatment / all                          | 0 / 5                                                  | 0 / 3                                                 | 0 / 3                                                 |
| Metastases to bone                                                  |                                                        |                                                       |                                                       |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                          | 0 / 11 (0.00%)                                        | 0 / 12 (0.00%)                                        |
| occurrences causally related to treatment / all                     | 0 / 0                                                  | 0 / 0                                                 | 0 / 0                                                 |
| deaths causally related to treatment / all                          | 0 / 0                                                  | 0 / 0                                                 | 0 / 0                                                 |
| Metastases to spine                                                 |                                                        |                                                       |                                                       |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                          | 1 / 11 (9.09%)                                        | 0 / 12 (0.00%)                                        |
| occurrences causally related to treatment / all                     | 0 / 0                                                  | 0 / 1                                                 | 0 / 0                                                 |
| deaths causally related to treatment / all                          | 0 / 0                                                  | 0 / 0                                                 | 0 / 0                                                 |
| Metastatic malignant melanoma                                       |                                                        |                                                       |                                                       |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                          | 0 / 11 (0.00%)                                        | 0 / 12 (0.00%)                                        |
| occurrences causally related to treatment / all                     | 0 / 0                                                  | 0 / 0                                                 | 0 / 0                                                 |
| deaths causally related to treatment / all                          | 0 / 0                                                  | 0 / 0                                                 | 0 / 0                                                 |
| Neoplasm malignant                                                  |                                                        |                                                       |                                                       |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                          | 0 / 11 (0.00%)                                        | 0 / 12 (0.00%)                                        |
| occurrences causally related to treatment / all                     | 0 / 0                                                  | 0 / 0                                                 | 0 / 0                                                 |
| deaths causally related to treatment / all                          | 0 / 0                                                  | 0 / 0                                                 | 0 / 0                                                 |
| Neoplasm progression                                                |                                                        |                                                       |                                                       |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tumour haemorrhage                              |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tumour pain                                     |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Vascular disorders                              |               |                |                |
| Arterial haemorrhage                            |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Bleeding varicose vein                          |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Deep vein thrombosis                            |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Embolism                                        |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemorrhage                                     |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypotension                                     |               |                |                |

|                                                      |                |                |                |
|------------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Vasculitis                                           |                |                |                |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Peripheral embolism                                  |                |                |                |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |                |                |                |
| Fatigue                                              |                |                |                |
| subjects affected / exposed                          | 2 / 9 (22.22%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 1 / 3          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Oedema peripheral                                    |                |                |                |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Pain                                                 |                |                |                |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Performance status decreased                         |                |                |                |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Pyrexia                                              |                |                |                |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Sudden death                                         |                |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Systemic inflammatory response syndrome         |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |               |                |                |
| Acute respiratory failure                       |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Atelectasis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Dyspnoea                                        |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypoxia                                         |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pleural effusion                                |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pleuritic pain                                  |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumothorax                                    |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumonitis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pulmonary embolism                              |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Respiratory distress                            |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Respiratory failure                             |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Psychiatric disorders                           |               |                |                |
| Confusional state                               |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Investigations                                  |               |                |                |
| Alanine aminotransferase increased              |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Aspartate aminotransferase increased            |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| Blood alkaline phosphatase increased            |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Blood bilirubin increased                       |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Blood creatinine increased                      |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Liver function test increased                   |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Transaminases increased                         |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Troponin I increased                            |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Injury, poisoning and procedural complications  |                |                |                |
| Fall                                            |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hip fracture                                    |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| Humerus fracture                                |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Subdural haematoma                              |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Cardiac disorders                               |                |                |                |
| Acute myocardial infarction                     |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Arrhythmia                                      |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Atrial fibrillation                             |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Cardiac tamponade                               |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Cardio-respiratory arrest                       |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Immune-mediated myocarditis                     |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Myocardial infarction                           |                |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myocardial ischaemia                            |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myocarditis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pericardial effusion                            |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Supraventricular tachycardia                    |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nervous system disorders                        |               |                |                |
| Brain oedema                                    |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebral haemorrhage                            |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebral infarction                             |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebrovascular accident                        |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebral ischaemia                              |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Facial paresis                                  |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemorrhage intracranial                        |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Headache                                        |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Seizure                                         |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Paraparesis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Somnolence                                      |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Syncope                                         |               |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Transient ischaemic attack                      |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Tremor                                          |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Blood and lymphatic system disorders            |                |                |                |
| Anaemia                                         |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Aplasia pure red cell                           |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Febrile neutropenia                             |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Haemolysis                                      |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Haemolytic anaemia                              |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Heparin-induced thrombocytopenia                |                |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pancytopenia                                    |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Ear and labyrinth disorders                     |                |                |                |
| Vertigo                                         |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Eye disorders                                   |                |                |                |
| Uveitis                                         |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                      |                |                |                |
| Abdominal pain                                  |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Ascites                                         |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Autoimmune colitis                              |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Colitis                                         |                |                |                |
| subjects affected / exposed                     | 2 / 9 (22.22%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 3 / 3          | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Colitis ulcerative                              |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Diarrhoea                                       |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Duodenal ulcer                                  |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Dysphagia                                       |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastric haemorrhage                             |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastrointestinal haemorrhage                    |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated enterocolitis                   |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Intestinal obstruction                          |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Intestinal perforation                          |               |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Lower gastrointestinal haemorrhage              |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Nausea                                          |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Odynophagia                                     |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Oesophagitis                                    |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pancreatitis                                    |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pancreatitis acute                              |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Portal hypertensive gastropathy                 |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Small intestinal obstruction                    |                |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 2          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Small intestinal perforation                    |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Upper gastrointestinal haemorrhage              |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Vomiting                                        |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hepatobiliary disorders                         |                |                |                |
| Cholecystitis                                   |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Cholecystitis acute                             |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hepatitis                                       |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hepatotoxicity                                  |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hypertransaminasaemia                           |                |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Immune-mediated hepatic disorder                |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Immune-mediated hepatitis                       |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Jaundice cholestatic                            |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders          |                |                |                |
| Acute generalised exanthematous pustulosis      |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Rash                                            |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Rash maculo-papular                             |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Renal and urinary disorders                     |                |                |                |
| Acute kidney injury                             |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Immune-mediated nephritis                       |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nephrolithiasis                                 |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Renal failure                                   |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Urinary tract obstruction                       |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tubulointerstitial nephritis                    |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Endocrine disorders                             |               |                |                |
| Adrenal insufficiency                           |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 2 / 2          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hyperthyroidism                                 |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypophysitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypopituitarism                                 |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated hypophysitis                    |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Thyroiditis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Musculoskeletal and connective tissue disorders |               |                |                |
| Back pain                                       |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haematoma muscle                                |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Musculoskeletal chest pain                      |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myositis                                        |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pathological fracture                           |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Spinal stenosis                                 |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Infections and infestations</b>              |               |                |                |
| <b>Bacteraemia</b>                              |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>COVID-19</b>                                 |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>COVID-19 pneumonia</b>                       |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Clostridium difficile colitis</b>            |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Device related infection</b>                 |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Encephalitis</b>                             |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Enterocolitis infectious</b>                 |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Gastroenteritis</b>                          |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastrointestinal infection                      |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Klebsiella urinary tract infection              |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Listeriosis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumonia                                       |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumonia influenzal                            |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Post procedural infection                       |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Postoperative wound infection                   |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pulmonary sepsis                                |               |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pyelonephritis                                  |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pyelonephritis acute                            |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Respiratory tract infection                     |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Sepsis                                          |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Septic shock                                    |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Staphylococcal bacteraemia                      |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Upper respiratory tract infection               |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Urinary tract infection                         |                |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Urosepsis                                       |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Viral infection                                 |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |               |                |                |
| Diabetes mellitus                               |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Diabetic ketoacidosis                           |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypercalcaemia                                  |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hyperglycaemia                                  |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypocalcaemia                                   |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypoglycaemia                                   |               |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hyponatraemia                                   |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Malnutrition                                    |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

| <b>Serious adverse events</b>                                       | Part 1B: BMS-986249 1200mg Q8W+ Nivolumab Combination | Part 1B: BMS-986249 1600mg Q8W+ Nivolumab Combination | Part 2A: Melanoma Arms BMS-986249 240mg IV Q3W |
|---------------------------------------------------------------------|-------------------------------------------------------|-------------------------------------------------------|------------------------------------------------|
| Total subjects affected by serious adverse events                   |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 7 / 9 (77.78%)                                        | 8 / 10 (80.00%)                                       | 3 / 3 (100.00%)                                |
| number of deaths (all causes)                                       | 4                                                     | 9                                                     | 0                                              |
| number of deaths resulting from adverse events                      | 3                                                     | 2                                                     | 0                                              |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                                       |                                                       |                                                |
| Malignant neoplasm progression                                      |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 2 / 9 (22.22%)                                        | 2 / 10 (20.00%)                                       | 0 / 3 (0.00%)                                  |
| occurrences causally related to treatment / all                     | 0 / 2                                                 | 0 / 2                                                 | 0 / 0                                          |
| deaths causally related to treatment / all                          | 0 / 2                                                 | 0 / 2                                                 | 0 / 0                                          |
| Metastases to bone                                                  |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                         | 0 / 10 (0.00%)                                        | 0 / 3 (0.00%)                                  |
| occurrences causally related to treatment / all                     | 0 / 0                                                 | 0 / 0                                                 | 0 / 0                                          |
| deaths causally related to treatment / all                          | 0 / 0                                                 | 0 / 0                                                 | 0 / 0                                          |
| Metastases to spine                                                 |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                         | 0 / 10 (0.00%)                                        | 0 / 3 (0.00%)                                  |
| occurrences causally related to treatment / all                     | 0 / 0                                                 | 0 / 0                                                 | 0 / 0                                          |
| deaths causally related to treatment / all                          | 0 / 0                                                 | 0 / 0                                                 | 0 / 0                                          |
| Metastatic malignant melanoma                                       |                                                       |                                                       |                                                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Neoplasm malignant                              |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Neoplasm progression                            |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 1 / 3 (33.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Tumour haemorrhage                              |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 1          | 0 / 0          | 0 / 0          |
| Tumour pain                                     |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Vascular disorders                              |                |                |                |
| Arterial haemorrhage                            |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Bleeding varicose vein                          |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Deep vein thrombosis                            |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Embolism                                        |                |                |                |

|                                                      |               |                |               |
|------------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                          | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0         |
| Haemorrhage                                          |               |                |               |
| subjects affected / exposed                          | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0         |
| Hypotension                                          |               |                |               |
| subjects affected / exposed                          | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0         |
| Vasculitis                                           |               |                |               |
| subjects affected / exposed                          | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0         |
| Peripheral embolism                                  |               |                |               |
| subjects affected / exposed                          | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0         |
| General disorders and administration site conditions |               |                |               |
| Fatigue                                              |               |                |               |
| subjects affected / exposed                          | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0         |
| Oedema peripheral                                    |               |                |               |
| subjects affected / exposed                          | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0         |
| Pain                                                 |               |                |               |
| subjects affected / exposed                          | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0         |
| Performance status decreased                         |               |                |               |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pyrexia                                         |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Sudden death                                    |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Systemic inflammatory response syndrome         |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |               |                |                |
| Acute respiratory failure                       |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Atelectasis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Dyspnoea                                        |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 1 / 3 (33.33%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypoxia                                         |               |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pleural effusion                                |               |                |                |

|                                                 |               |                 |               |
|-------------------------------------------------|---------------|-----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0         |
| Pleuritic pain                                  |               |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0         |
| Pneumothorax                                    |               |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0         |
| Pneumonitis                                     |               |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0         |
| Pulmonary embolism                              |               |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0         |
| Respiratory distress                            |               |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0         |
| Respiratory failure                             |               |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0         |
| Psychiatric disorders                           |               |                 |               |
| Confusional state                               |               |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0         |
| Investigations                                  |               |                 |               |

|                                                 |                |                 |               |
|-------------------------------------------------|----------------|-----------------|---------------|
| Alanine aminotransferase increased              |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Aspartate aminotransferase increased            |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Blood alkaline phosphatase increased            |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Blood bilirubin increased                       |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Blood creatinine increased                      |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Liver function test increased                   |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Transaminases increased                         |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Troponin I increased                            |                |                 |               |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Injury, poisoning and procedural complications  |                |                 |               |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| Fall                                            |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hip fracture                                    |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Humerus fracture                                |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Subdural haematoma                              |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Cardiac disorders                               |               |                |               |
| Acute myocardial infarction                     |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Arrhythmia                                      |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Atrial fibrillation                             |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Cardiac tamponade                               |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Cardio-respiratory arrest                       |               |                |               |

|                                                 |                |                |               |
|-------------------------------------------------|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Immune-mediated myocarditis                     |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Myocardial infarction                           |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Myocardial ischaemia                            |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Myocarditis                                     |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Pericardial effusion                            |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Supraventricular tachycardia                    |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Nervous system disorders                        |                |                |               |
| Brain oedema                                    |                |                |               |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Cerebral haemorrhage                            |                |                |               |

|                                                 |                |                |               |
|-------------------------------------------------|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Cerebral infarction                             |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Cerebrovascular accident                        |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Cerebral ischaemia                              |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Facial paresis                                  |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Haemorrhage intracranial                        |                |                |               |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Headache                                        |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Seizure                                         |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Paraparesis                                     |                |                |               |

|                                                 |                |                |               |
|-------------------------------------------------|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Somnolence                                      |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Syncope                                         |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Transient ischaemic attack                      |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Tremor                                          |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Blood and lymphatic system disorders            |                |                |               |
| Anaemia                                         |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Aplasia pure red cell                           |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Febrile neutropenia                             |                |                |               |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Haemolysis                                      |                |                |               |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Haemolytic anaemia                              |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Heparin-induced thrombocytopenia                |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pancytopenia                                    |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Ear and labyrinth disorders                     |               |                |               |
| Vertigo                                         |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Eye disorders                                   |               |                |               |
| Uveitis                                         |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Gastrointestinal disorders                      |               |                |               |
| Abdominal pain                                  |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Ascites                                         |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |

|                                                 |                |                 |                |
|-------------------------------------------------|----------------|-----------------|----------------|
| Autoimmune colitis                              |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Colitis                                         |                |                 |                |
| subjects affected / exposed                     | 2 / 9 (22.22%) | 2 / 10 (20.00%) | 1 / 3 (33.33%) |
| occurrences causally related to treatment / all | 3 / 4          | 2 / 2           | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Colitis ulcerative                              |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Diarrhoea                                       |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 2 / 10 (20.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 4 / 4           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Duodenal ulcer                                  |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Dysphagia                                       |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Gastric haemorrhage                             |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Gastrointestinal haemorrhage                    |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Immune-mediated enterocolitis                   |                |                 |                |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Intestinal obstruction                          |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Intestinal perforation                          |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Lower gastrointestinal haemorrhage              |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Nausea                                          |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Odynophagia                                     |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Oesophagitis                                    |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pancreatitis                                    |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pancreatitis acute                              |               |                |               |

|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Portal hypertensive gastropathy                 |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Small intestinal obstruction                    |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Small intestinal perforation                    |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Upper gastrointestinal haemorrhage              |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Vomiting                                        |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 1 / 3 (33.33%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Hepatobiliary disorders                         |               |                 |                |
| Cholecystitis                                   |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Cholecystitis acute                             |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Hepatitis                                       |               |                 |                |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hepatotoxicity                                  |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hypertransaminasaemia                           |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Immune-mediated hepatic disorder                |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Immune-mediated hepatitis                       |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Jaundice cholestatic                            |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Skin and subcutaneous tissue disorders          |               |                |               |
| Acute generalised exanthematous pustulosis      |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Rash                                            |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Rash maculo-papular                             |               |                |               |

|                                                 |                |                 |               |
|-------------------------------------------------|----------------|-----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Renal and urinary disorders                     |                |                 |               |
| Acute kidney injury                             |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 2 / 10 (20.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 2           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Immune-mediated nephritis                       |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Nephrolithiasis                                 |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Renal failure                                   |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Urinary tract obstruction                       |                |                 |               |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Tubulointerstitial nephritis                    |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Endocrine disorders                             |                |                 |               |
| Adrenal insufficiency                           |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Hyperthyroidism                                 |                |                 |               |

|                                                 |                |                 |                |
|-------------------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Hypophysitis                                    |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 1 / 3 (33.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1           | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Hypopituitarism                                 |                |                 |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Immune-mediated hypophysitis                    |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Thyroiditis                                     |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Musculoskeletal and connective tissue disorders |                |                 |                |
| Back pain                                       |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Haematoma muscle                                |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Musculoskeletal chest pain                      |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Myositis                                        |                |                 |                |

|                                                 |                |                 |               |
|-------------------------------------------------|----------------|-----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Pathological fracture                           |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Spinal stenosis                                 |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Infections and infestations                     |                |                 |               |
| Bacteraemia                                     |                |                 |               |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| COVID-19                                        |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| COVID-19 pneumonia                              |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Clostridium difficile colitis                   |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Device related infection                        |                |                 |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0         |
| Encephalitis                                    |                |                 |               |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Enterocolitis infectious                        |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Gastroenteritis                                 |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Gastrointestinal infection                      |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Klebsiella urinary tract infection              |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Listeriosis                                     |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pneumonia                                       |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pneumonia influenzal                            |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Post procedural infection                       |               |                |               |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Postoperative wound infection                   |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pulmonary sepsis                                |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pyelonephritis                                  |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pyelonephritis acute                            |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Respiratory tract infection                     |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Sepsis                                          |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Septic shock                                    |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Staphylococcal bacteraemia                      |               |                |               |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Upper respiratory tract infection               |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Urinary tract infection                         |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Urosepsis                                       |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Viral infection                                 |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Metabolism and nutrition disorders              |               |                |               |
| Diabetes mellitus                               |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Diabetic ketoacidosis                           |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hypercalcaemia                                  |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hyperglycaemia                                  |               |                |               |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hypocalcaemia                                   |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hypoglycaemia                                   |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hyponatraemia                                   |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Malnutrition                                    |               |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |

| <b>Serious adverse events</b>                                       | Part 2A: Melanoma Arms BMS-986249 800mg IV Q3W | Part 2A: Melanoma Arms BMS-986249 1200mg IV Q3W | Part 2A: Melanoma Arms Ipilimumab 3mg/kg IV Q3W |
|---------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
| Total subjects affected by serious adverse events                   |                                                |                                                 |                                                 |
| subjects affected / exposed                                         | 1 / 3 (33.33%)                                 | 42 / 57 (73.68%)                                | 28 / 58 (48.28%)                                |
| number of deaths (all causes)                                       | 2                                              | 29                                              | 24                                              |
| number of deaths resulting from adverse events                      | 1                                              | 15                                              | 11                                              |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                                |                                                 |                                                 |
| Malignant neoplasm progression                                      |                                                |                                                 |                                                 |
| subjects affected / exposed                                         | 0 / 3 (0.00%)                                  | 6 / 57 (10.53%)                                 | 6 / 58 (10.34%)                                 |
| occurrences causally related to treatment / all                     | 0 / 0                                          | 0 / 6                                           | 0 / 6                                           |
| deaths causally related to treatment / all                          | 0 / 0                                          | 0 / 6                                           | 0 / 6                                           |
| Metastases to bone                                                  |                                                |                                                 |                                                 |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Metastases to spine                             |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Metastatic malignant melanoma                   |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 2          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Neoplasm malignant                              |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 3 / 57 (5.26%) | 2 / 58 (3.45%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 3          | 0 / 2          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 3          | 0 / 2          |
| Neoplasm progression                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tumour haemorrhage                              |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tumour pain                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Vascular disorders                              |               |                |                |
| Arterial haemorrhage                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Bleeding varicose vein                          |               |                |                |

|                                                      |               |                |                |
|------------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0          |
| Deep vein thrombosis                                 |               |                |                |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0          |
| Embolism                                             |               |                |                |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemorrhage                                          |               |                |                |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypotension                                          |               |                |                |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0          |
| Vasculitis                                           |               |                |                |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0          |
| Peripheral embolism                                  |               |                |                |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |               |                |                |
| Fatigue                                              |               |                |                |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0          |
| Oedema peripheral                                    |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pain                                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Performance status decreased                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pyrexia                                         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 5 / 57 (8.77%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 6 / 9          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Sudden death                                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 1          |
| Systemic inflammatory response syndrome         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 2 / 2          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |               |                |                |
| Acute respiratory failure                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Atelectasis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Dyspnoea                                        |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypoxia                                         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pleural effusion                                |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pleuritic pain                                  |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumothorax                                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumonitis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pulmonary embolism                              |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Respiratory distress                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Respiratory failure                             |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 2 / 57 (3.51%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 2          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 1          | 0 / 0          |
| Psychiatric disorders                           |               |                |                |
| Confusional state                               |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Investigations                                  |               |                |                |
| Alanine aminotransferase increased              |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Aspartate aminotransferase increased            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Blood alkaline phosphatase increased            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Blood bilirubin increased                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Blood creatinine increased                      |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Liver function test increased                   |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| Transaminases increased                         |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Troponin I increased                            |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Injury, poisoning and procedural complications  |                |                |                |
| Fall                                            |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hip fracture                                    |                |                |                |
| subjects affected / exposed                     | 1 / 3 (33.33%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Humerus fracture                                |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Subdural haematoma                              |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Cardiac disorders                               |                |                |                |
| Acute myocardial infarction                     |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 2 / 58 (3.45%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 2          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Arrhythmia                                      |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Atrial fibrillation                             |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cardiac tamponade                               |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cardio-respiratory arrest                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 2 / 57 (3.51%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 2          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 1          | 0 / 0          |
| Immune-mediated myocarditis                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myocardial infarction                           |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myocardial ischaemia                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myocarditis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pericardial effusion                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Supraventricular tachycardia                    |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nervous system disorders                        |               |                |                |
| Brain oedema                                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebral haemorrhage                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebral infarction                             |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebrovascular accident                        |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 2 / 58 (3.45%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 2          | 0 / 2          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 1          |
| Cerebral ischaemia                              |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Facial paresis                                  |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemorrhage intracranial                        |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Headache                                        |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Seizure                                         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Paraparesis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Somnolence                                      |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Syncope                                         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Transient ischaemic attack                      |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tremor                                          |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Blood and lymphatic system disorders            |               |                |                |
| Anaemia                                         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Aplasia pure red cell                           |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Febrile neutropenia                             |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemolysis                                      |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemolytic anaemia                              |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Heparin-induced thrombocytopenia                |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pancytopenia                                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Ear and labyrinth disorders                     |               |                |                |
| Vertigo                                         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Eye disorders                                   |               |                |                |
| Uveitis                                         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                      |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Abdominal pain                                  |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Ascites                                         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Autoimmune colitis                              |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Colitis                                         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 2 / 57 (3.51%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 4 / 4          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Colitis ulcerative                              |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Diarrhoea                                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 2 / 57 (3.51%) | 3 / 58 (5.17%) |
| occurrences causally related to treatment / all | 0 / 0         | 2 / 2          | 3 / 3          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Duodenal ulcer                                  |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Dysphagia                                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastric haemorrhage                             |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastrointestinal haemorrhage                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated enterocolitis                   |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 3 / 57 (5.26%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 4 / 4          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Intestinal obstruction                          |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Intestinal perforation                          |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Lower gastrointestinal haemorrhage              |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nausea                                          |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Odynophagia                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Oesophagitis                                    |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pancreatitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pancreatitis acute                              |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Portal hypertensive gastropathy                 |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Small intestinal obstruction                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Small intestinal perforation                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 2          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Upper gastrointestinal haemorrhage              |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 2          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Vomiting                                        |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hepatobiliary disorders                         |               |                |                |
| Cholecystitis                                   |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cholecystitis acute                             |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hepatitis                                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 2 / 57 (3.51%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 2 / 2          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hepatotoxicity                                  |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypertransaminasaemia                           |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated hepatic disorder                |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated hepatitis                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 2 / 58 (3.45%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 2 / 2          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Jaundice cholestatic                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders          |               |                |                |
| Acute generalised exanthematous pustulosis      |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 2 / 2          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Rash                                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Rash maculo-papular                             |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Renal and urinary disorders                     |               |                |                |
| Acute kidney injury                             |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated nephritis                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nephrolithiasis                                 |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Renal failure                                   |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Urinary tract obstruction                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tubulointerstitial nephritis                    |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Endocrine disorders                             |               |                |                |
| Adrenal insufficiency                           |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hyperthyroidism                                 |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypophysitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypopituitarism                                 |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated hypophysitis                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Thyroiditis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Musculoskeletal and connective tissue disorders |               |                |                |
| Back pain                                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| Haematoma muscle                                |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Musculoskeletal chest pain                      |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Myositis                                        |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pathological fracture                           |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 2 / 58 (3.45%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 2          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Spinal stenosis                                 |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                |                |                |
| Bacteraemia                                     |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| COVID-19                                        |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| COVID-19 pneumonia                              |                |                |                |
| subjects affected / exposed                     | 1 / 3 (33.33%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 1          | 0 / 1          | 0 / 0          |
| Clostridium difficile colitis                   |                |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Device related infection                        |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Encephalitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Enterocolitis infectious                        |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastroenteritis                                 |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastrointestinal infection                      |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Klebsiella urinary tract infection              |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Listeriosis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 1          | 0 / 0          |
| Pneumonia                                       |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 2 / 57 (3.51%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 2          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 2          | 0 / 0          |
| Pneumonia influenzal                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Post procedural infection                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Postoperative wound infection                   |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pulmonary sepsis                                |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pyelonephritis                                  |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pyelonephritis acute                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Respiratory tract infection                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Sepsis                                          |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 2 / 58 (3.45%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 2          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 1          |
| Septic shock                                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Staphylococcal bacteraemia                      |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Upper respiratory tract infection               |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Urinary tract infection                         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 2 / 57 (3.51%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 2          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Urosepsis                                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Viral infection                                 |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |               |                |                |
| Diabetes mellitus                               |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Diabetic ketoacidosis                           |               |                |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypercalcaemia                                  |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hyperglycaemia                                  |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypocalcaemia                                   |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypoglycaemia                                   |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hyponatraemia                                   |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Malnutrition                                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

| Serious adverse events                            | Part 2A: Melanoma Arms Nivolumab Mono | Part 2A: Melanoma Arms BMS-986249 600mg IV Q8W | Part 2B: Cohort 1 (HCC) |
|---------------------------------------------------|---------------------------------------|------------------------------------------------|-------------------------|
| Total subjects affected by serious adverse events |                                       |                                                |                         |
| subjects affected / exposed                       | 1 / 3 (33.33%)                        | 20 / 36 (55.56%)                               | 5 / 5 (100.00%)         |
| number of deaths (all causes)                     | 1                                     | 11                                             | 4                       |
| number of deaths resulting from adverse events    | 1                                     | 3                                              | 2                       |

|                                                                     |                |                |                |
|---------------------------------------------------------------------|----------------|----------------|----------------|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                |                |                |
| Malignant neoplasm progression                                      |                |                |                |
| subjects affected / exposed                                         | 1 / 3 (33.33%) | 3 / 36 (8.33%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all                     | 0 / 1          | 0 / 3          | 0 / 1          |
| deaths causally related to treatment / all                          | 0 / 1          | 0 / 3          | 0 / 0          |
| Metastases to bone                                                  |                |                |                |
| subjects affected / exposed                                         | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0          |
| Metastases to spine                                                 |                |                |                |
| subjects affected / exposed                                         | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0          |
| Metastatic malignant melanoma                                       |                |                |                |
| subjects affected / exposed                                         | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0          |
| Neoplasm malignant                                                  |                |                |                |
| subjects affected / exposed                                         | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 1          |
| Neoplasm progression                                                |                |                |                |
| subjects affected / exposed                                         | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0          |
| Tumour haemorrhage                                                  |                |                |                |
| subjects affected / exposed                                         | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0          |
| Tumour pain                                                         |                |                |                |
| subjects affected / exposed                                         | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0          |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Vascular disorders                              |               |                |                |
| Arterial haemorrhage                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Bleeding varicose vein                          |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Deep vein thrombosis                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Embolism                                        |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemorrhage                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypotension                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Vasculitis                                      |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Peripheral embolism                             |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| General disorders and administration            |               |                |                |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| site conditions                                 |               |                |               |
| Fatigue                                         |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Oedema peripheral                               |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pain                                            |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Performance status decreased                    |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pyrexia                                         |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 2 / 4          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Sudden death                                    |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Systemic inflammatory response syndrome         |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Respiratory, thoracic and mediastinal disorders |               |                |               |
| Acute respiratory failure                       |               |                |               |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Atelectasis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Dyspnoea                                        |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypoxia                                         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pleural effusion                                |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pleuritic pain                                  |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumothorax                                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumonitis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pulmonary embolism                              |               |                |                |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Respiratory distress                            |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Respiratory failure                             |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Psychiatric disorders                           |               |                |               |
| Confusional state                               |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Investigations                                  |               |                |               |
| Alanine aminotransferase increased              |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Aspartate aminotransferase increased            |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Blood alkaline phosphatase increased            |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Blood bilirubin increased                       |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| Blood creatinine increased                      |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Liver function test increased                   |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Transaminases increased                         |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Troponin I increased                            |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Injury, poisoning and procedural complications  |               |                |               |
| Fall                                            |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hip fracture                                    |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Humerus fracture                                |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Subdural haematoma                              |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| Cardiac disorders                               |               |                |               |
| Acute myocardial infarction                     |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Arrhythmia                                      |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Atrial fibrillation                             |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Cardiac tamponade                               |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Cardio-respiratory arrest                       |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Immune-mediated myocarditis                     |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Myocardial infarction                           |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Myocardial ischaemia                            |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Myocarditis                                     |               |                |               |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pericardial effusion                            |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Supraventricular tachycardia                    |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Nervous system disorders                        |               |                |               |
| Brain oedema                                    |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Cerebral haemorrhage                            |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Cerebral infarction                             |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Cerebrovascular accident                        |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Cerebral ischaemia                              |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Facial paresis                                  |               |                |               |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Haemorrhage intracranial                        |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Headache                                        |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Seizure                                         |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Paraparesis                                     |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Somnolence                                      |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Syncope                                         |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Transient ischaemic attack                      |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Tremor                                          |               |                |               |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Blood and lymphatic system disorders</b>     |               |                |                |
| <b>Anaemia</b>                                  |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Aplasia pure red cell</b>                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Febrile neutropenia</b>                      |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Haemolysis</b>                               |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Haemolytic anaemia</b>                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Heparin-induced thrombocytopenia</b>         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Pancytopenia</b>                             |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Ear and labyrinth disorders</b>              |               |                |                |

|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| Vertigo                                         |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Eye disorders                                   |               |                 |                |
| Uveitis                                         |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Gastrointestinal disorders                      |               |                 |                |
| Abdominal pain                                  |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Ascites                                         |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Autoimmune colitis                              |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Colitis                                         |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 2 / 36 (5.56%)  | 2 / 5 (40.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 2 / 2           | 3 / 3          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Colitis ulcerative                              |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Diarrhoea                                       |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 4 / 36 (11.11%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 4 / 4           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| Duodenal ulcer                                  |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Dysphagia                                       |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Gastric haemorrhage                             |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Gastrointestinal haemorrhage                    |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Immune-mediated enterocolitis                   |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 2 / 36 (5.56%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 3 / 3          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Intestinal obstruction                          |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Intestinal perforation                          |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Lower gastrointestinal haemorrhage              |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Nausea                                          |               |                |               |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Odynophagia                                     |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Oesophagitis                                    |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pancreatitis                                    |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pancreatitis acute                              |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Portal hypertensive gastropathy                 |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Small intestinal obstruction                    |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Small intestinal perforation                    |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Upper gastrointestinal haemorrhage              |               |                |               |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Vomiting                                        |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hepatobiliary disorders                         |               |                |               |
| Cholecystitis                                   |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Cholecystitis acute                             |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hepatitis                                       |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hepatotoxicity                                  |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hypertransaminaemia                             |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 1 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Immune-mediated hepatic disorder                |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Immune-mediated hepatitis                       |               |                |               |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Jaundice cholestatic                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders          |               |                |                |
| Acute generalised exanthematous pustulosis      |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Rash                                            |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Rash maculo-papular                             |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Renal and urinary disorders                     |               |                |                |
| Acute kidney injury                             |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Immune-mediated nephritis                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nephrolithiasis                                 |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| Renal failure                                   |                |                |                |
| subjects affected / exposed                     | 1 / 3 (33.33%) | 0 / 36 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Urinary tract obstruction                       |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Tubulointerstitial nephritis                    |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Endocrine disorders                             |                |                |                |
| Adrenal insufficiency                           |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hyperthyroidism                                 |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hypophysitis                                    |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 36 (2.78%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hypopituitarism                                 |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Immune-mediated hypophysitis                    |                |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 36 (2.78%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Thyroiditis                                     |                |                |                |

|                                                        |               |                |                |
|--------------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Musculoskeletal and connective tissue disorders</b> |               |                |                |
| Back pain                                              |               |                |                |
| subjects affected / exposed                            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| Haematoma muscle                                       |               |                |                |
| subjects affected / exposed                            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| Musculoskeletal chest pain                             |               |                |                |
| subjects affected / exposed                            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| Myositis                                               |               |                |                |
| subjects affected / exposed                            | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all        | 0 / 0         | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| Pathological fracture                                  |               |                |                |
| subjects affected / exposed                            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| Spinal stenosis                                        |               |                |                |
| subjects affected / exposed                            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |
| <b>Infections and infestations</b>                     |               |                |                |
| Bacteraemia                                            |               |                |                |
| subjects affected / exposed                            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all        | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0         | 0 / 0          | 0 / 0          |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| COVID-19                                        |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| COVID-19 pneumonia                              |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Clostridium difficile colitis                   |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Device related infection                        |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Encephalitis                                    |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Enterocolitis infectious                        |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Gastroenteritis                                 |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Gastrointestinal infection                      |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Klebsiella urinary tract infection              |               |                |               |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Listeriosis                                     |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pneumonia                                       |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pneumonia influenzal                            |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Post procedural infection                       |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Postoperative wound infection                   |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pulmonary sepsis                                |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pyelonephritis                                  |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pyelonephritis acute                            |               |                |               |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Respiratory tract infection                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Sepsis                                          |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 1          |
| Septic shock                                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Staphylococcal bacteraemia                      |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Upper respiratory tract infection               |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Urinary tract infection                         |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Urosepsis                                       |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Viral infection                                 |               |                |                |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Metabolism and nutrition disorders              |               |                |               |
| Diabetes mellitus                               |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Diabetic ketoacidosis                           |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hypercalcaemia                                  |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hyperglycaemia                                  |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hypocalcaemia                                   |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hypoglycaemia                                   |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Hyponatraemia                                   |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Malnutrition                                    |               |                |               |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |

| <b>Serious adverse events</b>                                       | Part 2B: Cohort 2<br>(Metastatic CRPC) | Part 2B: Cohort 3<br>(Unresectable TNBC) |  |
|---------------------------------------------------------------------|----------------------------------------|------------------------------------------|--|
| Total subjects affected by serious adverse events                   |                                        |                                          |  |
| subjects affected / exposed                                         | 29 / 41 (70.73%)                       | 25 / 45 (55.56%)                         |  |
| number of deaths (all causes)                                       | 26                                     | 28                                       |  |
| number of deaths resulting from adverse events                      | 13                                     | 10                                       |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                        |                                          |  |
| Malignant neoplasm progression                                      |                                        |                                          |  |
| subjects affected / exposed                                         | 4 / 41 (9.76%)                         | 2 / 45 (4.44%)                           |  |
| occurrences causally related to treatment / all                     | 0 / 4                                  | 0 / 2                                    |  |
| deaths causally related to treatment / all                          | 0 / 4                                  | 0 / 2                                    |  |
| Metastases to bone                                                  |                                        |                                          |  |
| subjects affected / exposed                                         | 0 / 41 (0.00%)                         | 0 / 45 (0.00%)                           |  |
| occurrences causally related to treatment / all                     | 0 / 0                                  | 0 / 0                                    |  |
| deaths causally related to treatment / all                          | 0 / 0                                  | 0 / 0                                    |  |
| Metastases to spine                                                 |                                        |                                          |  |
| subjects affected / exposed                                         | 0 / 41 (0.00%)                         | 0 / 45 (0.00%)                           |  |
| occurrences causally related to treatment / all                     | 0 / 0                                  | 0 / 0                                    |  |
| deaths causally related to treatment / all                          | 0 / 0                                  | 0 / 0                                    |  |
| Metastatic malignant melanoma                                       |                                        |                                          |  |
| subjects affected / exposed                                         | 0 / 41 (0.00%)                         | 0 / 45 (0.00%)                           |  |
| occurrences causally related to treatment / all                     | 0 / 0                                  | 0 / 0                                    |  |
| deaths causally related to treatment / all                          | 0 / 0                                  | 0 / 0                                    |  |
| Neoplasm malignant                                                  |                                        |                                          |  |
| subjects affected / exposed                                         | 4 / 41 (9.76%)                         | 5 / 45 (11.11%)                          |  |
| occurrences causally related to treatment / all                     | 0 / 4                                  | 0 / 5                                    |  |
| deaths causally related to treatment / all                          | 0 / 4                                  | 0 / 5                                    |  |
| Neoplasm progression                                                |                                        |                                          |  |
| subjects affected / exposed                                         | 0 / 41 (0.00%)                         | 0 / 45 (0.00%)                           |  |
| occurrences causally related to treatment / all                     | 0 / 0                                  | 0 / 0                                    |  |
| deaths causally related to treatment / all                          | 0 / 0                                  | 0 / 0                                    |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| Tumour haemorrhage                              |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Tumour pain                                     |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Vascular disorders                              |                |                |  |
| Arterial haemorrhage                            |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Bleeding varicose vein                          |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Deep vein thrombosis                            |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Embolism                                        |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Haemorrhage                                     |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hypotension                                     |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Vasculitis                                      |                |                |  |

|                                                      |                |                |  |
|------------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                          | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Peripheral embolism                                  |                |                |  |
| subjects affected / exposed                          | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| General disorders and administration site conditions |                |                |  |
| Fatigue                                              |                |                |  |
| subjects affected / exposed                          | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Oedema peripheral                                    |                |                |  |
| subjects affected / exposed                          | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Pain                                                 |                |                |  |
| subjects affected / exposed                          | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Performance status decreased                         |                |                |  |
| subjects affected / exposed                          | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Pyrexia                                              |                |                |  |
| subjects affected / exposed                          | 2 / 41 (4.88%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 2          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Sudden death                                         |                |                |  |
| subjects affected / exposed                          | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Systemic inflammatory response syndrome              |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Respiratory, thoracic and mediastinal disorders |                |                |  |
| Acute respiratory failure                       |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Atelectasis                                     |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Dyspnoea                                        |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hypoxia                                         |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pleural effusion                                |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 3 / 45 (6.67%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 3          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pleuritic pain                                  |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pneumothorax                                    |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pneumonitis                                     |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pulmonary embolism                              |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Respiratory distress                            |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Respiratory failure                             |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Psychiatric disorders                           |                |                |  |
| Confusional state                               |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Investigations                                  |                |                |  |
| Alanine aminotransferase increased              |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Aspartate aminotransferase increased            |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Blood alkaline phosphatase increased            |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| Blood bilirubin increased                       |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Blood creatinine increased                      |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Liver function test increased                   |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Transaminases increased                         |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Troponin I increased                            |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Injury, poisoning and procedural complications  |                |                |  |
| Fall                                            |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hip fracture                                    |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Humerus fracture                                |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| Subdural haematoma                              |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Cardiac disorders                               |                |                |  |
| Acute myocardial infarction                     |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Arrhythmia                                      |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Atrial fibrillation                             |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Cardiac tamponade                               |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 1          | 0 / 0          |  |
| Cardio-respiratory arrest                       |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Immune-mediated myocarditis                     |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Myocardial infarction                           |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Myocardial ischaemia                            |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Myocarditis                                     |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pericardial effusion                            |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Supraventricular tachycardia                    |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Nervous system disorders                        |                |                |  |
| Brain oedema                                    |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Cerebral haemorrhage                            |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 1          | 0 / 0          |  |
| Cerebral infarction                             |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Cerebrovascular accident                        |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 1          | 0 / 0          |  |
| Cerebral ischaemia                              |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Facial paresis                                  |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Haemorrhage intracranial                        |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Headache                                        |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Seizure                                         |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Paraparesis                                     |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Somnolence                                      |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Syncope                                         |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Transient ischaemic attack                      |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Tremor                                          |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Blood and lymphatic system disorders            |                |                |  |
| Anaemia                                         |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Aplasia pure red cell                           |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Febrile neutropenia                             |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Haemolysis                                      |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Haemolytic anaemia                              |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Heparin-induced thrombocytopenia                |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pancytopenia                                    |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Ear and labyrinth disorders                     |                |                |  |
| Vertigo                                         |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Eye disorders                                   |                |                |  |
| Uveitis                                         |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Gastrointestinal disorders                      |                |                |  |
| Abdominal pain                                  |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Ascites                                         |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Autoimmune colitis                              |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Colitis                                         |                |                |  |
| subjects affected / exposed                     | 2 / 41 (4.88%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 2 / 2          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Colitis ulcerative                              |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| Diarrhoea                                       |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 2 / 45 (4.44%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 2          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Duodenal ulcer                                  |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Dysphagia                                       |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Gastric haemorrhage                             |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Gastrointestinal haemorrhage                    |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Immune-mediated enterocolitis                   |                |                |  |
| subjects affected / exposed                     | 2 / 41 (4.88%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 2 / 2          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Intestinal obstruction                          |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Intestinal perforation                          |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Lower gastrointestinal haemorrhage              |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Nausea                                          |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Odynophagia                                     |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Oesophagitis                                    |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pancreatitis                                    |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pancreatitis acute                              |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Portal hypertensive gastropathy                 |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Small intestinal obstruction                    |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Small intestinal perforation                    |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Upper gastrointestinal haemorrhage              |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Vomiting                                        |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hepatobiliary disorders                         |                |                |  |
| Cholecystitis                                   |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Cholecystitis acute                             |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hepatitis                                       |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hepatotoxicity                                  |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hypertransaminaemia                             |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Immune-mediated hepatic disorder                |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Immune-mediated hepatitis                       |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Jaundice cholestatic                            |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 2          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 1          |  |
| Skin and subcutaneous tissue disorders          |                |                |  |
| Acute generalised exanthematous pustulosis      |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Rash                                            |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Rash maculo-papular                             |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Renal and urinary disorders                     |                |                |  |
| Acute kidney injury                             |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Immune-mediated nephritis                       |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| Nephrolithiasis                                 |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Renal failure                                   |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Urinary tract obstruction                       |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Tubulointerstitial nephritis                    |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Endocrine disorders                             |                |                |  |
| Adrenal insufficiency                           |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hyperthyroidism                                 |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hypophysitis                                    |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hypopituitarism                                 |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Immune-mediated hypophysitis                    |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Thyroiditis                                     |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Musculoskeletal and connective tissue disorders |                |                |  |
| Back pain                                       |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Haematoma muscle                                |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 1          |  |
| Musculoskeletal chest pain                      |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Myositis                                        |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pathological fracture                           |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Spinal stenosis                                 |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Infections and infestations                     |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| Bacteraemia                                     |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| COVID-19                                        |                |                |  |
| subjects affected / exposed                     | 2 / 41 (4.88%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 2          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| COVID-19 pneumonia                              |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Clostridium difficile colitis                   |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 1          |  |
| Device related infection                        |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Encephalitis                                    |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Enterocolitis infectious                        |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Gastroenteritis                                 |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Gastrointestinal infection                      |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Klebsiella urinary tract infection              |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Listeriosis                                     |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pneumonia                                       |                |                |  |
| subjects affected / exposed                     | 2 / 41 (4.88%) | 3 / 45 (6.67%) |  |
| occurrences causally related to treatment / all | 0 / 2          | 0 / 3          |  |
| deaths causally related to treatment / all      | 0 / 1          | 0 / 0          |  |
| Pneumonia influenzal                            |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Post procedural infection                       |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Postoperative wound infection                   |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pulmonary sepsis                                |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 1          | 0 / 0          |  |
| Pyelonephritis                                  |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pyelonephritis acute                            |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Respiratory tract infection                     |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Sepsis                                          |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Septic shock                                    |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Staphylococcal bacteraemia                      |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Upper respiratory tract infection               |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Urinary tract infection                         |                |                |  |
| subjects affected / exposed                     | 3 / 41 (7.32%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 5          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Urosepsis                                       |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 2 / 41 (4.88%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 2          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Viral infection                                 |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Metabolism and nutrition disorders              |                |                |  |
| Diabetes mellitus                               |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Diabetic ketoacidosis                           |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hypercalcaemia                                  |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hyperglycaemia                                  |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hypocalcaemia                                   |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hypoglycaemia                                   |                |                |  |
| subjects affected / exposed                     | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hyponatraemia                                   |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 2 / 41 (4.88%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 2          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Malnutrition                                    |                |                |  |
| subjects affected / exposed                     | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

Frequency threshold for reporting non-serious adverse events: 5 %

| <b>Non-serious adverse events</b>                                   | Part 1A: BMS-986249<br>Monotherapy 2400 Q4W | Part 1A: BMS-986249<br>Monotherapy 1600 Q4W | Part 1A: BMS-986249<br>Monotherapy BMS 800 Q4W |
|---------------------------------------------------------------------|---------------------------------------------|---------------------------------------------|------------------------------------------------|
| Total subjects affected by non-serious adverse events               |                                             |                                             |                                                |
| subjects affected / exposed                                         | 1 / 1 (100.00%)                             | 9 / 10 (90.00%)                             | 11 / 11 (100.00%)                              |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                             |                                             |                                                |
| Acrochordon                                                         |                                             |                                             |                                                |
| subjects affected / exposed                                         | 0 / 1 (0.00%)                               | 1 / 10 (10.00%)                             | 0 / 11 (0.00%)                                 |
| occurrences (all)                                                   | 0                                           | 1                                           | 0                                              |
| Malignant neoplasm progression                                      |                                             |                                             |                                                |
| subjects affected / exposed                                         | 0 / 1 (0.00%)                               | 0 / 10 (0.00%)                              | 0 / 11 (0.00%)                                 |
| occurrences (all)                                                   | 0                                           | 0                                           | 0                                              |
| Cancer pain                                                         |                                             |                                             |                                                |
| subjects affected / exposed                                         | 0 / 1 (0.00%)                               | 0 / 10 (0.00%)                              | 0 / 11 (0.00%)                                 |
| occurrences (all)                                                   | 0                                           | 0                                           | 0                                              |
| Tumour pain                                                         |                                             |                                             |                                                |
| subjects affected / exposed                                         | 0 / 1 (0.00%)                               | 0 / 10 (0.00%)                              | 0 / 11 (0.00%)                                 |
| occurrences (all)                                                   | 0                                           | 0                                           | 0                                              |
| Metastases to central nervous system                                |                                             |                                             |                                                |
| subjects affected / exposed                                         | 0 / 1 (0.00%)                               | 0 / 10 (0.00%)                              | 0 / 11 (0.00%)                                 |
| occurrences (all)                                                   | 0                                           | 0                                           | 0                                              |
| Vascular disorders                                                  |                                             |                                             |                                                |
| Deep vein thrombosis                                                |                                             |                                             |                                                |
| subjects affected / exposed                                         | 0 / 1 (0.00%)                               | 0 / 10 (0.00%)                              | 2 / 11 (18.18%)                                |
| occurrences (all)                                                   | 0                                           | 0                                           | 2                                              |
| Haematoma                                                           |                                             |                                             |                                                |

|                                                      |               |                 |                |
|------------------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed                          | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%) |
| occurrences (all)                                    | 0             | 1               | 0              |
| Haemorrhage                                          |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                                    | 0             | 0               | 0              |
| Hot flush                                            |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                                    | 0             | 0               | 0              |
| Hypertension                                         |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)                                    | 0             | 0               | 1              |
| Hypotension                                          |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                                    | 0             | 0               | 0              |
| Pallor                                               |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                                    | 0             | 0               | 0              |
| Venous thrombosis                                    |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                                    | 0             | 0               | 0              |
| General disorders and administration site conditions |               |                 |                |
| Asthenia                                             |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                                    | 0             | 0               | 0              |
| Application site reaction                            |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                                    | 0             | 0               | 0              |
| Axillary pain                                        |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                                    | 0             | 0               | 0              |
| Chest discomfort                                     |               |                 |                |
| subjects affected / exposed                          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                                    | 0             | 0               | 0              |
| Chest pain                                           |               |                 |                |

|                                     |               |                 |                 |
|-------------------------------------|---------------|-----------------|-----------------|
| subjects affected / exposed         | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%)  |
| occurrences (all)                   | 0             | 1               | 0               |
| Chills                              |               |                 |                 |
| subjects affected / exposed         | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                   | 0             | 0               | 0               |
| Complication associated with device |               |                 |                 |
| subjects affected / exposed         | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                   | 0             | 0               | 0               |
| Device related thrombosis           |               |                 |                 |
| subjects affected / exposed         | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                   | 0             | 0               | 0               |
| Gait disturbance                    |               |                 |                 |
| subjects affected / exposed         | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                   | 0             | 0               | 0               |
| Fatigue                             |               |                 |                 |
| subjects affected / exposed         | 0 / 1 (0.00%) | 7 / 10 (70.00%) | 4 / 11 (36.36%) |
| occurrences (all)                   | 0             | 7               | 5               |
| Hernia pain                         |               |                 |                 |
| subjects affected / exposed         | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                   | 0             | 0               | 0               |
| Injection site extravasation        |               |                 |                 |
| subjects affected / exposed         | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%)  |
| occurrences (all)                   | 0             | 1               | 0               |
| Influenza like illness              |               |                 |                 |
| subjects affected / exposed         | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                   | 0             | 0               | 0               |
| Localised oedema                    |               |                 |                 |
| subjects affected / exposed         | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                   | 0             | 0               | 0               |
| Mucosal inflammation                |               |                 |                 |
| subjects affected / exposed         | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                   | 0             | 0               | 0               |
| Malaise                             |               |                 |                 |
| subjects affected / exposed         | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                   | 0             | 0               | 0               |
| Non-cardiac chest pain              |               |                 |                 |

|                                          |               |                 |                |
|------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed              | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                        | 0             | 0               | 0              |
| Oedema peripheral                        |               |                 |                |
| subjects affected / exposed              | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 1 / 11 (9.09%) |
| occurrences (all)                        | 0             | 1               | 1              |
| Pain                                     |               |                 |                |
| subjects affected / exposed              | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                        | 0             | 0               | 0              |
| Performance status decreased             |               |                 |                |
| subjects affected / exposed              | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                        | 0             | 0               | 0              |
| Peripheral swelling                      |               |                 |                |
| subjects affected / exposed              | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)                        | 0             | 0               | 1              |
| Pyrexia                                  |               |                 |                |
| subjects affected / exposed              | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 1 / 11 (9.09%) |
| occurrences (all)                        | 0             | 1               | 1              |
| Swelling face                            |               |                 |                |
| subjects affected / exposed              | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)                        | 0             | 0               | 1              |
| Xerosis                                  |               |                 |                |
| subjects affected / exposed              | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                        | 0             | 0               | 0              |
| Temperature intolerance                  |               |                 |                |
| subjects affected / exposed              | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                        | 0             | 0               | 0              |
| Immune system disorders                  |               |                 |                |
| Seasonal allergy                         |               |                 |                |
| subjects affected / exposed              | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                        | 0             | 0               | 0              |
| Reproductive system and breast disorders |               |                 |                |
| Heavy menstrual bleeding                 |               |                 |                |
| subjects affected / exposed              | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                        | 0             | 0               | 0              |
| Breast pain                              |               |                 |                |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                               | 0               | 0               | 1               |
| Vulvovaginal pruritus                           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                               | 0               | 0               | 1               |
| Respiratory, thoracic and mediastinal disorders |                 |                 |                 |
| Apnoea                                          |                 |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 0               | 0               |
| Cough                                           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%)   | 1 / 10 (10.00%) | 2 / 11 (18.18%) |
| occurrences (all)                               | 0               | 1               | 2               |
| Dysphonia                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 0               | 0               |
| Dyspnoea                                        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%)   | 1 / 10 (10.00%) | 1 / 11 (9.09%)  |
| occurrences (all)                               | 0               | 1               | 2               |
| Nasal congestion                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%)   | 1 / 10 (10.00%) | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 1               | 0               |
| Hypoxia                                         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 0               | 0               |
| Haemoptysis                                     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 1 (100.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 1               | 0               | 0               |
| Oropharyngeal pain                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 0               | 0               |
| Pleural effusion                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                               | 0               | 0               | 1               |
| Pneumonitis                                     |                 |                 |                 |

|                                         |                 |                 |                |
|-----------------------------------------|-----------------|-----------------|----------------|
| subjects affected / exposed             | 0 / 1 (0.00%)   | 1 / 10 (10.00%) | 0 / 11 (0.00%) |
| occurrences (all)                       | 0               | 1               | 0              |
| Pneumothorax                            |                 |                 |                |
| subjects affected / exposed             | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)                       | 0               | 0               | 1              |
| Pulmonary embolism                      |                 |                 |                |
| subjects affected / exposed             | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                       | 0               | 0               | 0              |
| Rhinitis allergic                       |                 |                 |                |
| subjects affected / exposed             | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                       | 0               | 0               | 0              |
| Rhinorrhoea                             |                 |                 |                |
| subjects affected / exposed             | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                       | 0               | 0               | 0              |
| Upper-airway cough syndrome             |                 |                 |                |
| subjects affected / exposed             | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                       | 0               | 0               | 0              |
| Wheezing                                |                 |                 |                |
| subjects affected / exposed             | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                       | 0               | 0               | 0              |
| Psychiatric disorders                   |                 |                 |                |
| Adjustment disorder with depressed mood |                 |                 |                |
| subjects affected / exposed             | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                       | 0               | 0               | 0              |
| Affective disorder                      |                 |                 |                |
| subjects affected / exposed             | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                       | 0               | 0               | 0              |
| Anxiety                                 |                 |                 |                |
| subjects affected / exposed             | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                       | 0               | 0               | 0              |
| Depression                              |                 |                 |                |
| subjects affected / exposed             | 1 / 1 (100.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                       | 1               | 0               | 0              |
| Disorientation                          |                 |                 |                |

|                                      |                 |                 |                 |
|--------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed          | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Insomnia                             |                 |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Libido decreased                     |                 |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Mental status changes                |                 |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Panic attack                         |                 |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Investigations                       |                 |                 |                 |
| Ammonia increased                    |                 |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Alanine aminotransferase increased   |                 |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                    | 0               | 0               | 1               |
| Amylase increased                    |                 |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%)   | 1 / 10 (10.00%) | 1 / 11 (9.09%)  |
| occurrences (all)                    | 0               | 1               | 1               |
| Blood albumin decreased              |                 |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Aspartate aminotransferase increased |                 |                 |                 |
| subjects affected / exposed          | 1 / 1 (100.00%) | 1 / 10 (10.00%) | 2 / 11 (18.18%) |
| occurrences (all)                    | 1               | 1               | 2               |
| Blood bilirubin increased            |                 |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Blood alkaline phosphatase increased |                 |                 |                 |

|                                        |               |                 |                 |
|----------------------------------------|---------------|-----------------|-----------------|
| subjects affected / exposed            | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 3 / 11 (27.27%) |
| occurrences (all)                      | 0             | 0               | 3               |
| Blood calcium decreased                |               |                 |                 |
| subjects affected / exposed            | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                      | 0             | 0               | 0               |
| Blood calcium increased                |               |                 |                 |
| subjects affected / exposed            | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                      | 0             | 0               | 0               |
| Blood cholesterol increased            |               |                 |                 |
| subjects affected / exposed            | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                      | 0             | 0               | 0               |
| Blood creatine phosphokinase increased |               |                 |                 |
| subjects affected / exposed            | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                      | 0             | 0               | 0               |
| Blood creatinine increased             |               |                 |                 |
| subjects affected / exposed            | 0 / 1 (0.00%) | 2 / 10 (20.00%) | 1 / 11 (9.09%)  |
| occurrences (all)                      | 0             | 3               | 1               |
| Blood glucose decreased                |               |                 |                 |
| subjects affected / exposed            | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                      | 0             | 0               | 0               |
| Blood lactic acid increased            |               |                 |                 |
| subjects affected / exposed            | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                      | 0             | 0               | 0               |
| Blood glucose increased                |               |                 |                 |
| subjects affected / exposed            | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                      | 0             | 0               | 0               |
| Blood magnesium decreased              |               |                 |                 |
| subjects affected / exposed            | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                      | 0             | 0               | 0               |
| Blood phosphorus increased             |               |                 |                 |
| subjects affected / exposed            | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                      | 0             | 0               | 0               |
| Blood potassium decreased              |               |                 |                 |
| subjects affected / exposed            | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                      | 0             | 0               | 0               |

|                                             |                 |                 |                 |
|---------------------------------------------|-----------------|-----------------|-----------------|
| Blood prolactin increased                   |                 |                 |                 |
| subjects affected / exposed                 | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 0               | 0               | 0               |
| Blood sodium decreased                      |                 |                 |                 |
| subjects affected / exposed                 | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 0               | 0               | 0               |
| Blood thyroid stimulating hormone decreased |                 |                 |                 |
| subjects affected / exposed                 | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                           | 0               | 0               | 1               |
| Blood thyroid stimulating hormone increased |                 |                 |                 |
| subjects affected / exposed                 | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 0               | 0               | 0               |
| Blood uric acid increased                   |                 |                 |                 |
| subjects affected / exposed                 | 0 / 1 (0.00%)   | 1 / 10 (10.00%) | 0 / 11 (0.00%)  |
| occurrences (all)                           | 0               | 1               | 0               |
| C-reactive protein increased                |                 |                 |                 |
| subjects affected / exposed                 | 1 / 1 (100.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 1               | 0               | 0               |
| Cardiac murmur                              |                 |                 |                 |
| subjects affected / exposed                 | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 0               | 0               | 0               |
| Gamma-glutamyltransferase increased         |                 |                 |                 |
| subjects affected / exposed                 | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 0               | 0               | 0               |
| Haemoglobin decreased                       |                 |                 |                 |
| subjects affected / exposed                 | 1 / 1 (100.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 1               | 0               | 0               |
| International normalised ratio increased    |                 |                 |                 |
| subjects affected / exposed                 | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 0               | 0               | 0               |
| Lipase increased                            |                 |                 |                 |
| subjects affected / exposed                 | 1 / 1 (100.00%) | 1 / 10 (10.00%) | 2 / 11 (18.18%) |
| occurrences (all)                           | 1               | 1               | 4               |
| Liver function test increased               |                 |                 |                 |

|                                                |                 |                 |                 |
|------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                    | 1 / 1 (100.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                              | 1               | 0               | 0               |
| Neutrophil count decreased                     |                 |                 |                 |
| subjects affected / exposed                    | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                              | 0               | 0               | 0               |
| Platelet count decreased                       |                 |                 |                 |
| subjects affected / exposed                    | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                              | 0               | 0               | 0               |
| Troponin I increased                           |                 |                 |                 |
| subjects affected / exposed                    | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                              | 0               | 0               | 0               |
| Transaminases increased                        |                 |                 |                 |
| subjects affected / exposed                    | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                              | 0               | 0               | 0               |
| Troponin increased                             |                 |                 |                 |
| subjects affected / exposed                    | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                              | 0               | 0               | 0               |
| Urine phosphorus increased                     |                 |                 |                 |
| subjects affected / exposed                    | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                              | 0               | 0               | 0               |
| Urine calcium increased                        |                 |                 |                 |
| subjects affected / exposed                    | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                              | 0               | 0               | 0               |
| Weight decreased                               |                 |                 |                 |
| subjects affected / exposed                    | 0 / 1 (0.00%)   | 1 / 10 (10.00%) | 2 / 11 (18.18%) |
| occurrences (all)                              | 0               | 1               | 2               |
| White blood cell count decreased               |                 |                 |                 |
| subjects affected / exposed                    | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                              | 0               | 0               | 0               |
| White blood cell count increased               |                 |                 |                 |
| subjects affected / exposed                    | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                              | 0               | 0               | 1               |
| Injury, poisoning and procedural complications |                 |                 |                 |
| Fall                                           |                 |                 |                 |

|                               |               |                 |                |
|-------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)             | 0             | 0               | 1              |
| Femur fracture                |               |                 |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0               | 0              |
| Infusion related reaction     |               |                 |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 1 / 11 (9.09%) |
| occurrences (all)             | 0             | 1               | 1              |
| Muscle strain                 |               |                 |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0               | 0              |
| Lip injury                    |               |                 |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0               | 0              |
| Procedural pain               |               |                 |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 1 / 11 (9.09%) |
| occurrences (all)             | 0             | 1               | 1              |
| Rib fracture                  |               |                 |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0               | 0              |
| Skin abrasion                 |               |                 |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0               | 0              |
| Tooth fracture                |               |                 |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0               | 0              |
| Vascular access site erythema |               |                 |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 1               | 0              |
| Wound secretion               |               |                 |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0               | 0              |
| Cardiac disorders             |               |                 |                |
| Atrial fibrillation           |               |                 |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)             | 0             | 0               | 2              |

|                             |               |                 |                |
|-----------------------------|---------------|-----------------|----------------|
| Palpitations                |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Pericardial effusion        |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)           | 0             | 0               | 1              |
| Sinus bradycardia           |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Sinus tachycardia           |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Tachycardia                 |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Nervous system disorders    |               |                 |                |
| Aphasia                     |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Cognitive disorder          |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Dysarthria                  |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Dizziness                   |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 1               | 0              |
| Headache                    |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Dysgeusia                   |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Hyperaesthesia              |               |                 |                |

|                               |               |                |                |
|-------------------------------|---------------|----------------|----------------|
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Lethargy                      |               |                |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Neuralgia                     |               |                |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Neuropathy peripheral         |               |                |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Paraesthesia                  |               |                |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Parkinson's disease           |               |                |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Peripheral sensory neuropathy |               |                |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Peripheral motor neuropathy   |               |                |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Post herpetic neuralgia       |               |                |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Restless legs syndrome        |               |                |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Radiculopathy                 |               |                |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Somnolence                    |               |                |                |
| subjects affected / exposed   | 0 / 1 (0.00%) | 0 / 10 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Sciatica                      |               |                |                |

|                                      |               |                 |                 |
|--------------------------------------|---------------|-----------------|-----------------|
| subjects affected / exposed          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0               |
| Tension headache                     |               |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0               |
| Tremor                               |               |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                    | 0             | 0               | 1               |
| Blood and lymphatic system disorders |               |                 |                 |
| Anaemia                              |               |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%) | 3 / 10 (30.00%) | 3 / 11 (27.27%) |
| occurrences (all)                    | 0             | 4               | 3               |
| Eosinophilia                         |               |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0               |
| Iron deficiency anaemia              |               |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0               |
| Leukocytosis                         |               |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0               |
| Lymphopenia                          |               |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0               |
| Thrombocytopenia                     |               |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                    | 0             | 0               | 1               |
| Neutropenia                          |               |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0               |
| Ear and labyrinth disorders          |               |                 |                 |
| Ear pain                             |               |                 |                 |
| subjects affected / exposed          | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0               |
| Hypoacusis                           |               |                 |                 |

|                             |                 |                 |                |
|-----------------------------|-----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Vertigo                     |                 |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Eye disorders               |                 |                 |                |
| Dry eye                     |                 |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Iridocyclitis               |                 |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Eyelid irritation           |                 |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Vision blurred              |                 |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Swelling of eyelid          |                 |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Gastrointestinal disorders  |                 |                 |                |
| Abdominal discomfort        |                 |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Abdominal distension        |                 |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)           | 0               | 0               | 1              |
| Abdominal pain              |                 |                 |                |
| subjects affected / exposed | 1 / 1 (100.00%) | 1 / 10 (10.00%) | 1 / 11 (9.09%) |
| occurrences (all)           | 1               | 1               | 2              |
| Abdominal pain lower        |                 |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Abdominal pain upper        |                 |                 |                |

|                                    |               |                 |                 |
|------------------------------------|---------------|-----------------|-----------------|
| subjects affected / exposed        | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                  | 0             | 0               | 1               |
| Ascites                            |               |                 |                 |
| subjects affected / exposed        | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0               |
| Colitis                            |               |                 |                 |
| subjects affected / exposed        | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0               |
| Constipation                       |               |                 |                 |
| subjects affected / exposed        | 0 / 1 (0.00%) | 2 / 10 (20.00%) | 1 / 11 (9.09%)  |
| occurrences (all)                  | 0             | 2               | 1               |
| Diarrhoea                          |               |                 |                 |
| subjects affected / exposed        | 0 / 1 (0.00%) | 7 / 10 (70.00%) | 3 / 11 (27.27%) |
| occurrences (all)                  | 0             | 9               | 5               |
| Dyspepsia                          |               |                 |                 |
| subjects affected / exposed        | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0               |
| Dry mouth                          |               |                 |                 |
| subjects affected / exposed        | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0               |
| Dysphagia                          |               |                 |                 |
| subjects affected / exposed        | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0               |
| Enteritis                          |               |                 |                 |
| subjects affected / exposed        | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0               |
| Flatulence                         |               |                 |                 |
| subjects affected / exposed        | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0               |
| Frequent bowel movements           |               |                 |                 |
| subjects affected / exposed        | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0               |
| Gastritis                          |               |                 |                 |
| subjects affected / exposed        | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0               |
| Gastrointestinal motility disorder |               |                 |                 |

|                                  |               |                 |                 |
|----------------------------------|---------------|-----------------|-----------------|
| subjects affected / exposed      | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 0             | 0               | 0               |
| Gastrointestinal haemorrhage     |               |                 |                 |
| subjects affected / exposed      | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                | 0             | 0               | 1               |
| Gastrooesophageal reflux disease |               |                 |                 |
| subjects affected / exposed      | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 1 / 11 (9.09%)  |
| occurrences (all)                | 0             | 1               | 1               |
| Immune-mediated enterocolitis    |               |                 |                 |
| subjects affected / exposed      | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 0             | 0               | 0               |
| Impaired gastric emptying        |               |                 |                 |
| subjects affected / exposed      | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 0             | 0               | 0               |
| Mouth ulceration                 |               |                 |                 |
| subjects affected / exposed      | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 0             | 0               | 0               |
| Nausea                           |               |                 |                 |
| subjects affected / exposed      | 0 / 1 (0.00%) | 5 / 10 (50.00%) | 3 / 11 (27.27%) |
| occurrences (all)                | 0             | 6               | 3               |
| Oesophageal varices haemorrhage  |               |                 |                 |
| subjects affected / exposed      | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 0             | 0               | 0               |
| Oral dysaesthesia                |               |                 |                 |
| subjects affected / exposed      | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 0             | 0               | 0               |
| Proctalgia                       |               |                 |                 |
| subjects affected / exposed      | 0 / 1 (0.00%) | 2 / 10 (20.00%) | 0 / 11 (0.00%)  |
| occurrences (all)                | 0             | 2               | 0               |
| Rectal haemorrhage               |               |                 |                 |
| subjects affected / exposed      | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 0             | 0               | 0               |
| Stomatitis                       |               |                 |                 |
| subjects affected / exposed      | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 0             | 0               | 0               |
| Vomiting                         |               |                 |                 |

|                                                  |                    |                     |                      |
|--------------------------------------------------|--------------------|---------------------|----------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 1 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0 | 4 / 11 (36.36%)<br>5 |
| Hepatobiliary disorders                          |                    |                     |                      |
| Biliary obstruction                              |                    |                     |                      |
| subjects affected / exposed                      | 0 / 1 (0.00%)      | 0 / 10 (0.00%)      | 0 / 11 (0.00%)       |
| occurrences (all)                                | 0                  | 0                   | 0                    |
| Autoimmune hepatitis                             |                    |                     |                      |
| subjects affected / exposed                      | 0 / 1 (0.00%)      | 0 / 10 (0.00%)      | 0 / 11 (0.00%)       |
| occurrences (all)                                | 0                  | 0                   | 0                    |
| Hepatitis                                        |                    |                     |                      |
| subjects affected / exposed                      | 0 / 1 (0.00%)      | 0 / 10 (0.00%)      | 0 / 11 (0.00%)       |
| occurrences (all)                                | 0                  | 0                   | 0                    |
| Hepatic failure                                  |                    |                     |                      |
| subjects affected / exposed                      | 0 / 1 (0.00%)      | 0 / 10 (0.00%)      | 1 / 11 (9.09%)       |
| occurrences (all)                                | 0                  | 0                   | 1                    |
| Hyperbilirubinaemia                              |                    |                     |                      |
| subjects affected / exposed                      | 1 / 1 (100.00%)    | 0 / 10 (0.00%)      | 0 / 11 (0.00%)       |
| occurrences (all)                                | 1                  | 0                   | 0                    |
| Hypertransaminaemia                              |                    |                     |                      |
| subjects affected / exposed                      | 0 / 1 (0.00%)      | 0 / 10 (0.00%)      | 0 / 11 (0.00%)       |
| occurrences (all)                                | 0                  | 0                   | 0                    |
| Immune-mediated hepatitis                        |                    |                     |                      |
| subjects affected / exposed                      | 0 / 1 (0.00%)      | 0 / 10 (0.00%)      | 0 / 11 (0.00%)       |
| occurrences (all)                                | 0                  | 0                   | 0                    |
| Jaundice cholestatic                             |                    |                     |                      |
| subjects affected / exposed                      | 0 / 1 (0.00%)      | 0 / 10 (0.00%)      | 0 / 11 (0.00%)       |
| occurrences (all)                                | 0                  | 0                   | 0                    |
| Portal hypertension                              |                    |                     |                      |
| subjects affected / exposed                      | 0 / 1 (0.00%)      | 0 / 10 (0.00%)      | 0 / 11 (0.00%)       |
| occurrences (all)                                | 0                  | 0                   | 0                    |
| Skin and subcutaneous tissue disorders           |                    |                     |                      |
| Alopecia                                         |                    |                     |                      |
| subjects affected / exposed                      | 0 / 1 (0.00%)      | 0 / 10 (0.00%)      | 0 / 11 (0.00%)       |
| occurrences (all)                                | 0                  | 0                   | 0                    |
| Acquired porokeratosis                           |                    |                     |                      |

|                                          |                 |                 |                 |
|------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed              | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                        | 0               | 0               | 0               |
| <b>Dermatitis acneiform</b>              |                 |                 |                 |
| subjects affected / exposed              | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                        | 0               | 0               | 0               |
| <b>Drug eruption</b>                     |                 |                 |                 |
| subjects affected / exposed              | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                        | 0               | 0               | 0               |
| <b>Dry skin</b>                          |                 |                 |                 |
| subjects affected / exposed              | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                        | 0               | 0               | 1               |
| <b>Eczema</b>                            |                 |                 |                 |
| subjects affected / exposed              | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                        | 0               | 0               | 0               |
| <b>Erythema</b>                          |                 |                 |                 |
| subjects affected / exposed              | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                        | 0               | 0               | 0               |
| <b>Ecchymosis</b>                        |                 |                 |                 |
| subjects affected / exposed              | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                        | 0               | 0               | 1               |
| <b>Night sweats</b>                      |                 |                 |                 |
| subjects affected / exposed              | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                        | 0               | 0               | 0               |
| <b>Keloid scar</b>                       |                 |                 |                 |
| subjects affected / exposed              | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                        | 0               | 0               | 0               |
| <b>Leukoplakia</b>                       |                 |                 |                 |
| subjects affected / exposed              | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                        | 0               | 0               | 0               |
| <b>Rash</b>                              |                 |                 |                 |
| subjects affected / exposed              | 1 / 1 (100.00%) | 1 / 10 (10.00%) | 2 / 11 (18.18%) |
| occurrences (all)                        | 1               | 1               | 2               |
| <b>Pruritus</b>                          |                 |                 |                 |
| subjects affected / exposed              | 0 / 1 (0.00%)   | 1 / 10 (10.00%) | 2 / 11 (18.18%) |
| occurrences (all)                        | 0               | 1               | 2               |
| <b>Palmar-plantar erythrodysesthesia</b> |                 |                 |                 |

|                                   |               |                 |                |
|-----------------------------------|---------------|-----------------|----------------|
| syndrome                          |               |                 |                |
| subjects affected / exposed       | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                 | 0             | 0               | 0              |
| Rash maculo-papular               |               |                 |                |
| subjects affected / exposed       | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                 | 0             | 0               | 0              |
| Rash macular                      |               |                 |                |
| subjects affected / exposed       | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)                 | 0             | 0               | 1              |
| Rash erythematous                 |               |                 |                |
| subjects affected / exposed       | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)                 | 0             | 0               | 1              |
| Rash pruritic                     |               |                 |                |
| subjects affected / exposed       | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                 | 0             | 0               | 0              |
| Rash vesicular                    |               |                 |                |
| subjects affected / exposed       | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%) |
| occurrences (all)                 | 0             | 1               | 0              |
| Transient acantholytic dermatosis |               |                 |                |
| subjects affected / exposed       | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                 | 0             | 0               | 0              |
| Skin hypopigmentation             |               |                 |                |
| subjects affected / exposed       | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                 | 0             | 0               | 0              |
| Urticaria                         |               |                 |                |
| subjects affected / exposed       | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                 | 0             | 0               | 0              |
| Vitiligo                          |               |                 |                |
| subjects affected / exposed       | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                 | 0             | 0               | 0              |
| Renal and urinary disorders       |               |                 |                |
| Acute kidney injury               |               |                 |                |
| subjects affected / exposed       | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                 | 0             | 0               | 0              |
| Pollakiuria                       |               |                 |                |

|                                              |               |                 |                |
|----------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed                  | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                            | 0             | 0               | 0              |
| Proteinuria                                  |               |                 |                |
| subjects affected / exposed                  | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                            | 0             | 0               | 0              |
| Haematuria                                   |               |                 |                |
| subjects affected / exposed                  | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                            | 0             | 0               | 0              |
| Tubulointerstitial nephritis                 |               |                 |                |
| subjects affected / exposed                  | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                            | 0             | 0               | 0              |
| Endocrine disorders                          |               |                 |                |
| Adrenal insufficiency                        |               |                 |                |
| subjects affected / exposed                  | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                            | 0             | 0               | 0              |
| Autoimmune thyroiditis                       |               |                 |                |
| subjects affected / exposed                  | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                            | 0             | 0               | 0              |
| Hyperthyroidism                              |               |                 |                |
| subjects affected / exposed                  | 0 / 1 (0.00%) | 2 / 10 (20.00%) | 0 / 11 (0.00%) |
| occurrences (all)                            | 0             | 2               | 0              |
| Hypophysitis                                 |               |                 |                |
| subjects affected / exposed                  | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                            | 0             | 0               | 0              |
| Hypopituitarism                              |               |                 |                |
| subjects affected / exposed                  | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                            | 0             | 0               | 0              |
| Hypothyroidism                               |               |                 |                |
| subjects affected / exposed                  | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 1 / 11 (9.09%) |
| occurrences (all)                            | 0             | 1               | 1              |
| Thyroiditis                                  |               |                 |                |
| subjects affected / exposed                  | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                            | 0             | 0               | 0              |
| Inappropriate antidiuretic hormone secretion |               |                 |                |

|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                               | 0             | 0               | 0              |
| Musculoskeletal and connective tissue disorders |               |                 |                |
| Arthralgia                                      |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)                               | 0             | 0               | 1              |
| Back pain                                       |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 2 / 10 (20.00%) | 1 / 11 (9.09%) |
| occurrences (all)                               | 0             | 2               | 1              |
| Groin pain                                      |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                               | 0             | 0               | 0              |
| Hypercreatinaemia                               |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                               | 0             | 0               | 0              |
| Joint swelling                                  |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                               | 0             | 0               | 0              |
| Muscular weakness                               |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                               | 0             | 0               | 0              |
| Muscle spasms                                   |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                               | 0             | 0               | 0              |
| Musculoskeletal chest pain                      |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)                               | 0             | 0               | 1              |
| Myalgia                                         |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)                               | 0             | 0               | 1              |
| Myositis                                        |               |                 |                |
| subjects affected / exposed                     | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                               | 0             | 0               | 0              |
| Neck pain                                       |               |                 |                |

|                             |               |                 |                |
|-----------------------------|---------------|-----------------|----------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)           | 0             | 0               | 1              |
| Pain in extremity           |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 1               | 0              |
| Sacral pain                 |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Infections and infestations |               |                 |                |
| Bronchitis                  |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Campylobacter infection     |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| COVID-19                    |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Candida infection           |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Cellulitis                  |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Conjunctivitis              |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Cystitis                    |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Diverticulitis              |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Eye infection bacterial     |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |

|                             |               |                 |                |
|-----------------------------|---------------|-----------------|----------------|
| Folliculitis                |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Gastroenteritis             |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Hepatitis viral             |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Gastrointestinal infection  |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)           | 0             | 0               | 1              |
| Herpes zoster               |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Hordeolum                   |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Influenza                   |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Localised infection         |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Mucosal infection           |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 1               | 0              |
| Nasopharyngitis             |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Oral candidiasis            |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |
| Norovirus infection         |               |                 |                |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0             | 0               | 0              |

|                                    |                 |                 |                |
|------------------------------------|-----------------|-----------------|----------------|
| Pharyngitis                        |                 |                 |                |
| subjects affected / exposed        | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                  | 0               | 0               | 0              |
| Rash pustular                      |                 |                 |                |
| subjects affected / exposed        | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                  | 0               | 0               | 0              |
| Pneumonia                          |                 |                 |                |
| subjects affected / exposed        | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)                  | 0               | 0               | 1              |
| Soft tissue infection              |                 |                 |                |
| subjects affected / exposed        | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                  | 0               | 0               | 0              |
| Skin infection                     |                 |                 |                |
| subjects affected / exposed        | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                  | 0               | 0               | 0              |
| Spontaneous bacterial peritonitis  |                 |                 |                |
| subjects affected / exposed        | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                  | 0               | 0               | 0              |
| Upper respiratory tract infection  |                 |                 |                |
| subjects affected / exposed        | 1 / 1 (100.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)                  | 1               | 0               | 1              |
| Urinary tract infection            |                 |                 |                |
| subjects affected / exposed        | 0 / 1 (0.00%)   | 1 / 10 (10.00%) | 1 / 11 (9.09%) |
| occurrences (all)                  | 0               | 1               | 1              |
| Staphylococcal infection           |                 |                 |                |
| subjects affected / exposed        | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                  | 0               | 0               | 0              |
| Vascular access site infection     |                 |                 |                |
| subjects affected / exposed        | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                  | 0               | 0               | 0              |
| Viral infection                    |                 |                 |                |
| subjects affected / exposed        | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                  | 0               | 0               | 0              |
| Metabolism and nutrition disorders |                 |                 |                |
| Decreased appetite                 |                 |                 |                |

|                             |               |                 |                 |
|-----------------------------|---------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 1 (0.00%) | 4 / 10 (40.00%) | 3 / 11 (27.27%) |
| occurrences (all)           | 0             | 4               | 3               |
| Dehydration                 |               |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 1 / 11 (9.09%)  |
| occurrences (all)           | 0             | 1               | 1               |
| Electrolyte imbalance       |               |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 0             | 0               | 0               |
| Hyperglycaemia              |               |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 2 / 11 (18.18%) |
| occurrences (all)           | 0             | 0               | 2               |
| Hypercalcaemia              |               |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 1 / 11 (9.09%)  |
| occurrences (all)           | 0             | 1               | 1               |
| Hyperkalaemia               |               |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 0 / 11 (0.00%)  |
| occurrences (all)           | 0             | 3               | 0               |
| Hypermagnesaemia            |               |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)           | 0             | 0               | 1               |
| Hyperlipasaemia             |               |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 0             | 0               | 0               |
| Hyperuricaemia              |               |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 0             | 0               | 0               |
| Hypernatraemia              |               |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 10 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)           | 0             | 0               | 1               |
| Hypoalbuminaemia            |               |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 10 (10.00%) | 1 / 11 (9.09%)  |
| occurrences (all)           | 0             | 1               | 1               |
| Hypocalcaemia               |               |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%) | 2 / 10 (20.00%) | 1 / 11 (9.09%)  |
| occurrences (all)           | 0             | 3               | 1               |
| Hypochloraemia              |               |                 |                 |

|                             |                 |                 |                 |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 0               | 0               | 0               |
| Hypokalaemia                |                 |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%)   | 3 / 10 (30.00%) | 1 / 11 (9.09%)  |
| occurrences (all)           | 0               | 5               | 1               |
| Hypomagnesaemia             |                 |                 |                 |
| subjects affected / exposed | 1 / 1 (100.00%) | 2 / 10 (20.00%) | 2 / 11 (18.18%) |
| occurrences (all)           | 1               | 2               | 2               |
| Hyponatraemia               |                 |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%)   | 2 / 10 (20.00%) | 2 / 11 (18.18%) |
| occurrences (all)           | 0               | 2               | 2               |
| Hypovolaemia                |                 |                 |                 |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 1               | 0               | 0               |
| Hypophosphataemia           |                 |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%)   | 2 / 10 (20.00%) | 1 / 11 (9.09%)  |
| occurrences (all)           | 0               | 3               | 1               |
| Iron deficiency             |                 |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 0               | 0               | 0               |
| Malnutrition                |                 |                 |                 |
| subjects affected / exposed | 0 / 1 (0.00%)   | 0 / 10 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 0               | 0               | 0               |

| <b>Non-serious adverse events</b>                                   | Part 1A: BMS-986249<br>Monotherapy 240 mg IV Q4W | Part 1A: BMS-986249<br>Monotherapy 1600 Q8W | Part 1B: BMS-986249 800mg Q8W+ Nivolumab Combination |
|---------------------------------------------------------------------|--------------------------------------------------|---------------------------------------------|------------------------------------------------------|
| Total subjects affected by non-serious adverse events               |                                                  |                                             |                                                      |
| subjects affected / exposed                                         | 6 / 6 (100.00%)                                  | 9 / 11 (81.82%)                             | 12 / 13 (92.31%)                                     |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                                  |                                             |                                                      |
| Acrochordon                                                         |                                                  |                                             |                                                      |
| subjects affected / exposed                                         | 0 / 6 (0.00%)                                    | 0 / 11 (0.00%)                              | 0 / 13 (0.00%)                                       |
| occurrences (all)                                                   | 0                                                | 0                                           | 0                                                    |
| Malignant neoplasm progression                                      |                                                  |                                             |                                                      |
| subjects affected / exposed                                         | 0 / 6 (0.00%)                                    | 0 / 11 (0.00%)                              | 0 / 13 (0.00%)                                       |
| occurrences (all)                                                   | 0                                                | 0                                           | 0                                                    |
| Cancer pain                                                         |                                                  |                                             |                                                      |

|                                                      |               |                |                |
|------------------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                                    | 0             | 0              | 0              |
| Tumour pain                                          |               |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                                    | 0             | 0              | 0              |
| Metastases to central nervous system                 |               |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                                    | 0             | 0              | 0              |
| Vascular disorders                                   |               |                |                |
| Deep vein thrombosis                                 |               |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                                    | 0             | 0              | 0              |
| Haematoma                                            |               |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                                    | 0             | 0              | 0              |
| Haemorrhage                                          |               |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                                    | 0             | 0              | 0              |
| Hot flush                                            |               |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                                    | 0             | 0              | 1              |
| Hypertension                                         |               |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                                    | 0             | 0              | 1              |
| Hypotension                                          |               |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                                    | 0             | 0              | 1              |
| Pallor                                               |               |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                                    | 0             | 0              | 0              |
| Venous thrombosis                                    |               |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                                    | 0             | 0              | 0              |
| General disorders and administration site conditions |               |                |                |

|                                     |                |                 |                 |
|-------------------------------------|----------------|-----------------|-----------------|
| Asthenia                            |                |                 |                 |
| subjects affected / exposed         | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)                   | 0              | 0               | 3               |
| Application site reaction           |                |                 |                 |
| subjects affected / exposed         | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0               |
| Axillary pain                       |                |                 |                 |
| subjects affected / exposed         | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0               |
| Chest discomfort                    |                |                 |                 |
| subjects affected / exposed         | 1 / 6 (16.67%) | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)                   | 1              | 0               | 1               |
| Chest pain                          |                |                 |                 |
| subjects affected / exposed         | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0               |
| Chills                              |                |                 |                 |
| subjects affected / exposed         | 1 / 6 (16.67%) | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                   | 1              | 0               | 0               |
| Complication associated with device |                |                 |                 |
| subjects affected / exposed         | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0               |
| Device related thrombosis           |                |                 |                 |
| subjects affected / exposed         | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0               |
| Gait disturbance                    |                |                 |                 |
| subjects affected / exposed         | 1 / 6 (16.67%) | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                   | 1              | 0               | 0               |
| Fatigue                             |                |                 |                 |
| subjects affected / exposed         | 1 / 6 (16.67%) | 2 / 11 (18.18%) | 7 / 13 (53.85%) |
| occurrences (all)                   | 1              | 2               | 8               |
| Hernia pain                         |                |                 |                 |
| subjects affected / exposed         | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0               |
| Injection site extravasation        |                |                 |                 |
| subjects affected / exposed         | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0               |

|                              |                |                 |                 |
|------------------------------|----------------|-----------------|-----------------|
| Influenza like illness       |                |                 |                 |
| subjects affected / exposed  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0               |
| Localised oedema             |                |                 |                 |
| subjects affected / exposed  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0               |
| Mucosal inflammation         |                |                 |                 |
| subjects affected / exposed  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0               |
| Malaise                      |                |                 |                 |
| subjects affected / exposed  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0               |
| Non-cardiac chest pain       |                |                 |                 |
| subjects affected / exposed  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0               |
| Oedema peripheral            |                |                 |                 |
| subjects affected / exposed  | 0 / 6 (0.00%)  | 2 / 11 (18.18%) | 3 / 13 (23.08%) |
| occurrences (all)            | 0              | 2               | 3               |
| Pain                         |                |                 |                 |
| subjects affected / exposed  | 0 / 6 (0.00%)  | 2 / 11 (18.18%) | 0 / 13 (0.00%)  |
| occurrences (all)            | 0              | 2               | 0               |
| Performance status decreased |                |                 |                 |
| subjects affected / exposed  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0               |
| Peripheral swelling          |                |                 |                 |
| subjects affected / exposed  | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  | 0 / 13 (0.00%)  |
| occurrences (all)            | 0              | 1               | 0               |
| Pyrexia                      |                |                 |                 |
| subjects affected / exposed  | 1 / 6 (16.67%) | 0 / 11 (0.00%)  | 4 / 13 (30.77%) |
| occurrences (all)            | 1              | 0               | 4               |
| Swelling face                |                |                 |                 |
| subjects affected / exposed  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0               |
| Xerosis                      |                |                 |                 |
| subjects affected / exposed  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0               |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                         |                                                                                                                                                            |                                                                                                                                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Temperature intolerance<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                                            | 0 / 6 (0.00%)<br>0                                                                                                                                      | 0 / 11 (0.00%)<br>0                                                                                                                                        | 0 / 13 (0.00%)<br>0                                                                                                                                         |
| Immune system disorders<br>Seasonal allergy<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                        | 0 / 6 (0.00%)<br>0                                                                                                                                      | 0 / 11 (0.00%)<br>0                                                                                                                                        | 1 / 13 (7.69%)<br>1                                                                                                                                         |
| Reproductive system and breast disorders<br>Heavy menstrual bleeding<br>subjects affected / exposed<br>occurrences (all)<br><br>Breast pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Vulvovaginal pruritus<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                       | 0 / 6 (0.00%)<br>0<br><br>0 / 6 (0.00%)<br>0<br><br>0 / 6 (0.00%)<br>0                                                                                  | 0 / 11 (0.00%)<br>0<br><br>0 / 11 (0.00%)<br>0<br><br>0 / 11 (0.00%)<br>0                                                                                  | 0 / 13 (0.00%)<br>0<br><br>0 / 13 (0.00%)<br>0<br><br>0 / 13 (0.00%)<br>0                                                                                   |
| Respiratory, thoracic and mediastinal disorders<br>Apnoea<br>subjects affected / exposed<br>occurrences (all)<br><br>Cough<br>subjects affected / exposed<br>occurrences (all)<br><br>Dysphonia<br>subjects affected / exposed<br>occurrences (all)<br><br>Dyspnoea<br>subjects affected / exposed<br>occurrences (all)<br><br>Nasal congestion<br>subjects affected / exposed<br>occurrences (all)<br><br>Hypoxia<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0<br><br>1 / 6 (16.67%)<br>1<br><br>0 / 6 (0.00%)<br>0<br><br>1 / 6 (16.67%)<br>1<br><br>1 / 6 (16.67%)<br>1<br><br>0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0<br><br>1 / 11 (9.09%)<br>1<br><br>0 / 11 (0.00%)<br>0<br><br>1 / 11 (9.09%)<br>2<br><br>0 / 11 (0.00%)<br>0<br><br>0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0<br><br>0 / 13 (0.00%)<br>0<br><br>1 / 13 (7.69%)<br>1<br><br>0 / 13 (0.00%)<br>0<br><br>0 / 13 (0.00%)<br>0<br><br>2 / 13 (15.38%)<br>2 |

|                                         |                |                |                |
|-----------------------------------------|----------------|----------------|----------------|
| Haemoptysis                             |                |                |                |
| subjects affected / exposed             | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                       | 0              | 0              | 1              |
| Oropharyngeal pain                      |                |                |                |
| subjects affected / exposed             | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                       | 0              | 0              | 1              |
| Pleural effusion                        |                |                |                |
| subjects affected / exposed             | 0 / 6 (0.00%)  | 1 / 11 (9.09%) | 1 / 13 (7.69%) |
| occurrences (all)                       | 0              | 1              | 1              |
| Pneumonitis                             |                |                |                |
| subjects affected / exposed             | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                       | 0              | 0              | 0              |
| Pneumothorax                            |                |                |                |
| subjects affected / exposed             | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                       | 1              | 0              | 0              |
| Pulmonary embolism                      |                |                |                |
| subjects affected / exposed             | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                       | 0              | 0              | 0              |
| Rhinitis allergic                       |                |                |                |
| subjects affected / exposed             | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                       | 0              | 0              | 0              |
| Rhinorrhoea                             |                |                |                |
| subjects affected / exposed             | 0 / 6 (0.00%)  | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences (all)                       | 0              | 1              | 0              |
| Upper-airway cough syndrome             |                |                |                |
| subjects affected / exposed             | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                       | 0              | 0              | 0              |
| Wheezing                                |                |                |                |
| subjects affected / exposed             | 0 / 6 (0.00%)  | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences (all)                       | 0              | 1              | 0              |
| Psychiatric disorders                   |                |                |                |
| Adjustment disorder with depressed mood |                |                |                |
| subjects affected / exposed             | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                       | 0              | 0              | 0              |
| Affective disorder                      |                |                |                |

|                                    |                |                |                 |
|------------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0               |
| Anxiety                            |                |                |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%)  |
| occurrences (all)                  | 0              | 0              | 1               |
| Depression                         |                |                |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0               |
| Disorientation                     |                |                |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0               |
| Insomnia                           |                |                |                 |
| subjects affected / exposed        | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 1 / 13 (7.69%)  |
| occurrences (all)                  | 1              | 0              | 1               |
| Libido decreased                   |                |                |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%)  |
| occurrences (all)                  | 0              | 0              | 1               |
| Mental status changes              |                |                |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0               |
| Panic attack                       |                |                |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0               |
| Investigations                     |                |                |                 |
| Ammonia increased                  |                |                |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0               |
| Alanine aminotransferase increased |                |                |                 |
| subjects affected / exposed        | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 3 / 13 (23.08%) |
| occurrences (all)                  | 1              | 0              | 3               |
| Amylase increased                  |                |                |                 |
| subjects affected / exposed        | 2 / 6 (33.33%) | 0 / 11 (0.00%) | 1 / 13 (7.69%)  |
| occurrences (all)                  | 2              | 0              | 1               |
| Blood albumin decreased            |                |                |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0               |

|                                        |                |                |                |
|----------------------------------------|----------------|----------------|----------------|
| Aspartate aminotransferase increased   |                |                |                |
| subjects affected / exposed            | 1 / 6 (16.67%) | 1 / 11 (9.09%) | 1 / 13 (7.69%) |
| occurrences (all)                      | 1              | 1              | 1              |
| Blood bilirubin increased              |                |                |                |
| subjects affected / exposed            | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                      | 1              | 0              | 2              |
| Blood alkaline phosphatase increased   |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Blood calcium decreased                |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Blood calcium increased                |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Blood cholesterol increased            |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Blood creatine phosphokinase increased |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Blood creatinine increased             |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                      | 0              | 0              | 2              |
| Blood glucose decreased                |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Blood lactic acid increased            |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                      | 0              | 0              | 1              |
| Blood glucose increased                |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Blood magnesium decreased              |                |                |                |

|                                             |                |                |                |
|---------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Blood phosphorus increased                  |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Blood potassium decreased                   |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Blood prolactin increased                   |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Blood sodium decreased                      |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Blood thyroid stimulating hormone decreased |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Blood thyroid stimulating hormone increased |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 1              | 0              |
| Blood uric acid increased                   |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| C-reactive protein increased                |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Cardiac murmur                              |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Gamma-glutamyltransferase increased         |                |                |                |
| subjects affected / exposed                 | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 1              | 0              | 0              |
| Haemoglobin decreased                       |                |                |                |

|                                          |               |                |                 |
|------------------------------------------|---------------|----------------|-----------------|
| subjects affected / exposed              | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                        | 0             | 0              | 0               |
| International normalised ratio increased |               |                |                 |
| subjects affected / exposed              | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                        | 0             | 0              | 0               |
| Lipase increased                         |               |                |                 |
| subjects affected / exposed              | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 2 / 13 (15.38%) |
| occurrences (all)                        | 0             | 0              | 2               |
| Liver function test increased            |               |                |                 |
| subjects affected / exposed              | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                        | 0             | 0              | 0               |
| Neutrophil count decreased               |               |                |                 |
| subjects affected / exposed              | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                        | 0             | 0              | 0               |
| Platelet count decreased                 |               |                |                 |
| subjects affected / exposed              | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                        | 0             | 0              | 0               |
| Troponin I increased                     |               |                |                 |
| subjects affected / exposed              | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%)  |
| occurrences (all)                        | 0             | 0              | 1               |
| Transaminases increased                  |               |                |                 |
| subjects affected / exposed              | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                        | 0             | 0              | 0               |
| Troponin increased                       |               |                |                 |
| subjects affected / exposed              | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                        | 0             | 0              | 0               |
| Urine phosphorus increased               |               |                |                 |
| subjects affected / exposed              | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                        | 0             | 0              | 0               |
| Urine calcium increased                  |               |                |                 |
| subjects affected / exposed              | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                        | 0             | 0              | 0               |
| Weight decreased                         |               |                |                 |
| subjects affected / exposed              | 0 / 6 (0.00%) | 1 / 11 (9.09%) | 2 / 13 (15.38%) |
| occurrences (all)                        | 0             | 1              | 2               |

|                                                                                      |                     |                     |                      |
|--------------------------------------------------------------------------------------|---------------------|---------------------|----------------------|
| White blood cell count decreased<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0  |
| White blood cell count increased<br>subjects affected / exposed<br>occurrences (all) | 1 / 6 (16.67%)<br>1 | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0  |
| Injury, poisoning and procedural complications                                       |                     |                     |                      |
| Fall<br>subjects affected / exposed<br>occurrences (all)                             | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 1 / 13 (7.69%)<br>1  |
| Femur fracture<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0  |
| Infusion related reaction<br>subjects affected / exposed<br>occurrences (all)        | 1 / 6 (16.67%)<br>1 | 1 / 11 (9.09%)<br>1 | 2 / 13 (15.38%)<br>2 |
| Muscle strain<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0  |
| Lip injury<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0  |
| Procedural pain<br>subjects affected / exposed<br>occurrences (all)                  | 1 / 6 (16.67%)<br>1 | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0  |
| Rib fracture<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0  |
| Skin abrasion<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0  |
| Tooth fracture<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0  |
| Vascular access site erythema                                                        |                     |                     |                      |

|                             |               |                |                |
|-----------------------------|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Wound secretion             |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 1              | 0              |
| Cardiac disorders           |               |                |                |
| Atrial fibrillation         |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Palpitations                |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Pericardial effusion        |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)           | 0             | 0              | 1              |
| Sinus bradycardia           |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)           | 0             | 0              | 1              |
| Sinus tachycardia           |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Tachycardia                 |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Nervous system disorders    |               |                |                |
| Aphasia                     |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Cognitive disorder          |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Dysarthria                  |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Dizziness                   |               |                |                |

|                               |                |                |                 |
|-------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed   | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)             | 1              | 0              | 0               |
| Headache                      |                |                |                 |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 1 / 11 (9.09%) | 3 / 13 (23.08%) |
| occurrences (all)             | 0              | 1              | 3               |
| Dysgeusia                     |                |                |                 |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%)  |
| occurrences (all)             | 0              | 0              | 1               |
| Hyperaesthesia                |                |                |                 |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0               |
| Lethargy                      |                |                |                 |
| subjects affected / exposed   | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)             | 1              | 0              | 0               |
| Neuralgia                     |                |                |                 |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0               |
| Neuropathy peripheral         |                |                |                 |
| subjects affected / exposed   | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)             | 1              | 0              | 0               |
| Paraesthesia                  |                |                |                 |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%)  |
| occurrences (all)             | 0              | 0              | 1               |
| Parkinson's disease           |                |                |                 |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0               |
| Peripheral sensory neuropathy |                |                |                 |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0               |
| Peripheral motor neuropathy   |                |                |                 |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0               |
| Post herpetic neuralgia       |                |                |                 |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0               |
| Restless legs syndrome        |                |                |                 |

|                                      |                |                |                 |
|--------------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |
| Radiculopathy                        |                |                |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |
| Somnolence                           |                |                |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |
| Sciatica                             |                |                |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |
| Tension headache                     |                |                |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |
| Tremor                               |                |                |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |
| Blood and lymphatic system disorders |                |                |                 |
| Anaemia                              |                |                |                 |
| subjects affected / exposed          | 1 / 6 (16.67%) | 1 / 11 (9.09%) | 5 / 13 (38.46%) |
| occurrences (all)                    | 1              | 1              | 5               |
| Eosinophilia                         |                |                |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |
| Iron deficiency anaemia              |                |                |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%)  |
| occurrences (all)                    | 0              | 0              | 1               |
| Leukocytosis                         |                |                |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%)  |
| occurrences (all)                    | 0              | 0              | 1               |
| Lymphopenia                          |                |                |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |
| Thrombocytopenia                     |                |                |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |

|                                                                          |                    |                     |                     |
|--------------------------------------------------------------------------|--------------------|---------------------|---------------------|
| Neutropenia<br>subjects affected / exposed<br>occurrences (all)          | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 |
| Ear and labyrinth disorders                                              |                    |                     |                     |
| Ear pain<br>subjects affected / exposed<br>occurrences (all)             | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 |
| Hypoacusis<br>subjects affected / exposed<br>occurrences (all)           | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 |
| Vertigo<br>subjects affected / exposed<br>occurrences (all)              | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 |
| Eye disorders                                                            |                    |                     |                     |
| Dry eye<br>subjects affected / exposed<br>occurrences (all)              | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 |
| Iridocyclitis<br>subjects affected / exposed<br>occurrences (all)        | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 |
| Eyelid irritation<br>subjects affected / exposed<br>occurrences (all)    | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 |
| Vision blurred<br>subjects affected / exposed<br>occurrences (all)       | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 |
| Swelling of eyelid<br>subjects affected / exposed<br>occurrences (all)   | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 |
| Gastrointestinal disorders                                               |                    |                     |                     |
| Abdominal discomfort<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 | 0 / 13 (0.00%)<br>0 |
| Abdominal distension<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0 | 1 / 11 (9.09%)<br>1 | 0 / 13 (0.00%)<br>0 |
| Abdominal pain                                                           |                    |                     |                     |

|                             |                |                 |                 |
|-----------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 3 / 6 (50.00%) | 2 / 11 (18.18%) | 3 / 13 (23.08%) |
| occurrences (all)           | 3              | 2               | 3               |
| Abdominal pain lower        |                |                 |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 1              | 0               | 0               |
| Abdominal pain upper        |                |                 |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)           | 1              | 0               | 1               |
| Ascites                     |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0               |
| Colitis                     |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)           | 0              | 0               | 1               |
| Constipation                |                |                 |                 |
| subjects affected / exposed | 3 / 6 (50.00%) | 5 / 11 (45.45%) | 6 / 13 (46.15%) |
| occurrences (all)           | 4              | 6               | 7               |
| Diarrhoea                   |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  | 2 / 13 (15.38%) |
| occurrences (all)           | 0              | 1               | 3               |
| Dyspepsia                   |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)           | 0              | 0               | 1               |
| Dry mouth                   |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)           | 0              | 0               | 1               |
| Dysphagia                   |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Enteritis                   |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)           | 0              | 0               | 1               |
| Flatulence                  |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Frequent bowel movements    |                |                 |                 |

|                                    |                |                 |                 |
|------------------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Gastritis                          |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 1               | 0               |
| Gastrointestinal motility disorder |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Gastrointestinal haemorrhage       |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Gastrooesophageal reflux disease   |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Immune-mediated enterocolitis      |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Impaired gastric emptying          |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)                  | 0              | 0               | 1               |
| Mouth ulceration                   |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Nausea                             |                |                 |                 |
| subjects affected / exposed        | 1 / 6 (16.67%) | 2 / 11 (18.18%) | 4 / 13 (30.77%) |
| occurrences (all)                  | 1              | 2               | 4               |
| Oesophageal varices haemorrhage    |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Oral dysaesthesia                  |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Proctalgia                         |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Rectal haemorrhage                 |                |                 |                 |

|                             |                |                 |                 |
|-----------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Stomatitis                  |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Vomiting                    |                |                 |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 2 / 11 (18.18%) | 3 / 13 (23.08%) |
| occurrences (all)           | 1              | 3               | 5               |
| Hepatobiliary disorders     |                |                 |                 |
| Biliary obstruction         |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Autoimmune hepatitis        |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Hepatitis                   |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)           | 0              | 0               | 2               |
| Hepatic failure             |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Hyperbilirubinaemia         |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)           | 0              | 0               | 1               |
| Hypertransaminaemia         |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)           | 0              | 0               | 2               |
| Immune-mediated hepatitis   |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Jaundice cholestatic        |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)           | 0              | 0               | 1               |
| Portal hypertension         |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |

|                                        |                |                |                |
|----------------------------------------|----------------|----------------|----------------|
| Skin and subcutaneous tissue disorders |                |                |                |
| Alopecia                               |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Acquired porokeratosis                 |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                      | 0              | 0              | 1              |
| Dermatitis acneiform                   |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Drug eruption                          |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Dry skin                               |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Eczema                                 |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Erythema                               |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Ecchymosis                             |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Night sweats                           |                |                |                |
| subjects affected / exposed            | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                      | 1              | 0              | 2              |
| Keloid scar                            |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Leukoplakia                            |                |                |                |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Rash                                   |                |                |                |

|                                             |                |                |                |
|---------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Pruritus                                    |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 1 / 11 (9.09%) | 1 / 13 (7.69%) |
| occurrences (all)                           | 0              | 1              | 3              |
| Palmar-plantar erythrodysaesthesia syndrome |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Rash maculo-papular                         |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                           | 0              | 0              | 1              |
| Rash macular                                |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Rash erythematous                           |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Rash pruritic                               |                |                |                |
| subjects affected / exposed                 | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 1              | 0              | 0              |
| Rash vesicular                              |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Transient acantholytic dermatosis           |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                           | 0              | 0              | 1              |
| Skin hypopigmentation                       |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Urticaria                                   |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Vitiligo                                    |                |                |                |
| subjects affected / exposed                 | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |

|                              |               |                |                 |
|------------------------------|---------------|----------------|-----------------|
| Renal and urinary disorders  |               |                |                 |
| Acute kidney injury          |               |                |                 |
| subjects affected / exposed  | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)            | 0             | 0              | 0               |
| Pollakiuria                  |               |                |                 |
| subjects affected / exposed  | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%)  |
| occurrences (all)            | 0             | 0              | 1               |
| Proteinuria                  |               |                |                 |
| subjects affected / exposed  | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)            | 0             | 0              | 0               |
| Haematuria                   |               |                |                 |
| subjects affected / exposed  | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)            | 0             | 0              | 0               |
| Tubulointerstitial nephritis |               |                |                 |
| subjects affected / exposed  | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)            | 0             | 0              | 0               |
| Endocrine disorders          |               |                |                 |
| Adrenal insufficiency        |               |                |                 |
| subjects affected / exposed  | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)            | 0             | 0              | 0               |
| Autoimmune thyroiditis       |               |                |                 |
| subjects affected / exposed  | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)            | 0             | 0              | 0               |
| Hyperthyroidism              |               |                |                 |
| subjects affected / exposed  | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 2 / 13 (15.38%) |
| occurrences (all)            | 0             | 0              | 2               |
| Hypophysitis                 |               |                |                 |
| subjects affected / exposed  | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%)  |
| occurrences (all)            | 0             | 0              | 1               |
| Hypopituitarism              |               |                |                 |
| subjects affected / exposed  | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%)  |
| occurrences (all)            | 0             | 0              | 0               |
| Hypothyroidism               |               |                |                 |
| subjects affected / exposed  | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 4 / 13 (30.77%) |
| occurrences (all)            | 0             | 0              | 4               |
| Thyroiditis                  |               |                |                 |

|                                                 |                |                 |                 |
|-------------------------------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)                               | 0              | 0               | 1               |
| Inappropriate antidiuretic hormone secretion    |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0               |
| Musculoskeletal and connective tissue disorders |                |                 |                 |
| Arthralgia                                      |                |                 |                 |
| subjects affected / exposed                     | 2 / 6 (33.33%) | 0 / 11 (0.00%)  | 2 / 13 (15.38%) |
| occurrences (all)                               | 2              | 0               | 3               |
| Back pain                                       |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 3 / 11 (27.27%) | 4 / 13 (30.77%) |
| occurrences (all)                               | 0              | 3               | 4               |
| Groin pain                                      |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0               |
| Hypercreatinaemia                               |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  | 0 / 13 (0.00%)  |
| occurrences (all)                               | 0              | 1               | 0               |
| Joint swelling                                  |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0               |
| Muscular weakness                               |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 3 / 13 (23.08%) |
| occurrences (all)                               | 0              | 0               | 3               |
| Muscle spasms                                   |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 2 / 11 (18.18%) | 0 / 13 (0.00%)  |
| occurrences (all)                               | 0              | 2               | 0               |
| Musculoskeletal chest pain                      |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0               |
| Myalgia                                         |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  | 1 / 13 (7.69%)  |
| occurrences (all)                               | 0              | 1               | 1               |
| Myositis                                        |                |                 |                 |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Neck pain                   |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Pain in extremity           |                |                |                |
| subjects affected / exposed | 1 / 6 (16.67%) | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences (all)           | 1              | 1              | 0              |
| Sacral pain                 |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Infections and infestations |                |                |                |
| Bronchitis                  |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Campylobacter infection     |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)           | 0              | 0              | 1              |
| COVID-19                    |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Candida infection           |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)           | 0              | 0              | 1              |
| Cellulitis                  |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Conjunctivitis              |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Cystitis                    |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Diverticulitis              |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |

|                             |               |                |                |
|-----------------------------|---------------|----------------|----------------|
| Eye infection bacterial     |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Folliculitis                |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Gastroenteritis             |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Hepatitis viral             |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Gastrointestinal infection  |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Herpes zoster               |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Hordeolum                   |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Influenza                   |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Localised infection         |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Mucosal infection           |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Nasopharyngitis             |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)           | 0             | 0              | 1              |
| Oral candidiasis            |               |                |                |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |

|                                   |                |                |                |
|-----------------------------------|----------------|----------------|----------------|
| Norovirus infection               |                |                |                |
| subjects affected / exposed       | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Pharyngitis                       |                |                |                |
| subjects affected / exposed       | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Rash pustular                     |                |                |                |
| subjects affected / exposed       | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                 | 0              | 0              | 1              |
| Pneumonia                         |                |                |                |
| subjects affected / exposed       | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Soft tissue infection             |                |                |                |
| subjects affected / exposed       | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Skin infection                    |                |                |                |
| subjects affected / exposed       | 1 / 6 (16.67%) | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                 | 1              | 0              | 0              |
| Spontaneous bacterial peritonitis |                |                |                |
| subjects affected / exposed       | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 1 / 13 (7.69%) |
| occurrences (all)                 | 0              | 0              | 1              |
| Upper respiratory tract infection |                |                |                |
| subjects affected / exposed       | 0 / 6 (0.00%)  | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences (all)                 | 0              | 1              | 0              |
| Urinary tract infection           |                |                |                |
| subjects affected / exposed       | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Staphylococcal infection          |                |                |                |
| subjects affected / exposed       | 0 / 6 (0.00%)  | 1 / 11 (9.09%) | 0 / 13 (0.00%) |
| occurrences (all)                 | 0              | 1              | 0              |
| Vascular access site infection    |                |                |                |
| subjects affected / exposed       | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Viral infection                   |                |                |                |
| subjects affected / exposed       | 0 / 6 (0.00%)  | 0 / 11 (0.00%) | 0 / 13 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |

|                                    |                |                 |                 |
|------------------------------------|----------------|-----------------|-----------------|
| Metabolism and nutrition disorders |                |                 |                 |
| Decreased appetite                 |                |                 |                 |
| subjects affected / exposed        | 2 / 6 (33.33%) | 2 / 11 (18.18%) | 4 / 13 (30.77%) |
| occurrences (all)                  | 2              | 2               | 4               |
| Dehydration                        |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 3 / 13 (23.08%) |
| occurrences (all)                  | 0              | 0               | 5               |
| Electrolyte imbalance              |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Hyperglycaemia                     |                |                 |                 |
| subjects affected / exposed        | 2 / 6 (33.33%) | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 2              | 0               | 0               |
| Hypercalcaemia                     |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Hyperkalaemia                      |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 1               | 0               |
| Hypermagnesaemia                   |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Hyperlipasaemia                    |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)                  | 0              | 0               | 1               |
| Hyperuricaemia                     |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Hypernatraemia                     |                |                 |                 |
| subjects affected / exposed        | 2 / 6 (33.33%) | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)                  | 2              | 0               | 0               |
| Hypoalbuminaemia                   |                |                 |                 |
| subjects affected / exposed        | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  | 2 / 13 (15.38%) |
| occurrences (all)                  | 0              | 1               | 2               |
| Hypocalcaemia                      |                |                 |                 |

|                             |                |                 |                 |
|-----------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Hypochloraemia              |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0               |
| Hypokalaemia                |                |                 |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 3 / 11 (27.27%) | 1 / 13 (7.69%)  |
| occurrences (all)           | 1              | 4               | 2               |
| Hypomagnesaemia             |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  | 2 / 13 (15.38%) |
| occurrences (all)           | 0              | 1               | 2               |
| Hyponatraemia               |                |                 |                 |
| subjects affected / exposed | 2 / 6 (33.33%) | 2 / 11 (18.18%) | 0 / 13 (0.00%)  |
| occurrences (all)           | 2              | 2               | 0               |
| Hypovolaemia                |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0               |
| Hypophosphataemia           |                |                 |                 |
| subjects affected / exposed | 2 / 6 (33.33%) | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)           | 2              | 0               | 1               |
| Iron deficiency             |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 1 / 13 (7.69%)  |
| occurrences (all)           | 0              | 0               | 1               |
| Malnutrition                |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  | 0 / 13 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |

| <b>Non-serious adverse events</b>                                   | Part 1B: BMS-986249 1200mg Q4W + Nivolumab Combination | Part 1B: BMS-986249 800mg Q4W + Nivolumab Combination | Part 1B: BMS-986249 240mg Q4W + Nivolumab Combination |
|---------------------------------------------------------------------|--------------------------------------------------------|-------------------------------------------------------|-------------------------------------------------------|
| Total subjects affected by non-serious adverse events               |                                                        |                                                       |                                                       |
| subjects affected / exposed                                         | 9 / 9 (100.00%)                                        | 11 / 11 (100.00%)                                     | 12 / 12 (100.00%)                                     |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                                        |                                                       |                                                       |
| Acrochordon                                                         |                                                        |                                                       |                                                       |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                          | 0 / 11 (0.00%)                                        | 0 / 12 (0.00%)                                        |
| occurrences (all)                                                   | 0                                                      | 0                                                     | 0                                                     |
| Malignant neoplasm progression                                      |                                                        |                                                       |                                                       |

|                                      |                |                |                |
|--------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed          | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                    | 1              | 0              | 0              |
| Cancer pain                          |                |                |                |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                    | 0              | 0              | 0              |
| Tumour pain                          |                |                |                |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                    | 0              | 0              | 0              |
| Metastases to central nervous system |                |                |                |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)                    | 0              | 0              | 1              |
| Vascular disorders                   |                |                |                |
| Deep vein thrombosis                 |                |                |                |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                    | 0              | 0              | 0              |
| Haematoma                            |                |                |                |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                    | 0              | 0              | 0              |
| Haemorrhage                          |                |                |                |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                    | 0              | 0              | 0              |
| Hot flush                            |                |                |                |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                    | 0              | 0              | 0              |
| Hypertension                         |                |                |                |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                    | 0              | 0              | 0              |
| Hypotension                          |                |                |                |
| subjects affected / exposed          | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                    | 1              | 0              | 0              |
| Pallor                               |                |                |                |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)                    | 0              | 1              | 0              |
| Venous thrombosis                    |                |                |                |

|                                                         |                    |                     |                     |
|---------------------------------------------------------|--------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)        | 0 / 9 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0 |
| General disorders and administration<br>site conditions |                    |                     |                     |
| Asthenia                                                |                    |                     |                     |
| subjects affected / exposed                             | 1 / 9 (11.11%)     | 1 / 11 (9.09%)      | 2 / 12 (16.67%)     |
| occurrences (all)                                       | 1                  | 1                   | 2                   |
| Application site reaction                               |                    |                     |                     |
| subjects affected / exposed                             | 0 / 9 (0.00%)      | 1 / 11 (9.09%)      | 0 / 12 (0.00%)      |
| occurrences (all)                                       | 0                  | 1                   | 0                   |
| Axillary pain                                           |                    |                     |                     |
| subjects affected / exposed                             | 1 / 9 (11.11%)     | 0 / 11 (0.00%)      | 0 / 12 (0.00%)      |
| occurrences (all)                                       | 1                  | 0                   | 0                   |
| Chest discomfort                                        |                    |                     |                     |
| subjects affected / exposed                             | 0 / 9 (0.00%)      | 0 / 11 (0.00%)      | 0 / 12 (0.00%)      |
| occurrences (all)                                       | 0                  | 0                   | 0                   |
| Chest pain                                              |                    |                     |                     |
| subjects affected / exposed                             | 0 / 9 (0.00%)      | 0 / 11 (0.00%)      | 0 / 12 (0.00%)      |
| occurrences (all)                                       | 0                  | 0                   | 0                   |
| Chills                                                  |                    |                     |                     |
| subjects affected / exposed                             | 0 / 9 (0.00%)      | 0 / 11 (0.00%)      | 1 / 12 (8.33%)      |
| occurrences (all)                                       | 0                  | 0                   | 1                   |
| Complication associated with device                     |                    |                     |                     |
| subjects affected / exposed                             | 0 / 9 (0.00%)      | 0 / 11 (0.00%)      | 1 / 12 (8.33%)      |
| occurrences (all)                                       | 0                  | 0                   | 1                   |
| Device related thrombosis                               |                    |                     |                     |
| subjects affected / exposed                             | 0 / 9 (0.00%)      | 1 / 11 (9.09%)      | 0 / 12 (0.00%)      |
| occurrences (all)                                       | 0                  | 1                   | 0                   |
| Gait disturbance                                        |                    |                     |                     |
| subjects affected / exposed                             | 0 / 9 (0.00%)      | 0 / 11 (0.00%)      | 0 / 12 (0.00%)      |
| occurrences (all)                                       | 0                  | 0                   | 0                   |
| Fatigue                                                 |                    |                     |                     |
| subjects affected / exposed                             | 6 / 9 (66.67%)     | 6 / 11 (54.55%)     | 9 / 12 (75.00%)     |
| occurrences (all)                                       | 7                  | 6                   | 9                   |
| Hernia pain                                             |                    |                     |                     |

|                              |                |                 |                 |
|------------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0               |
| Injection site extravasation |                |                 |                 |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0               |
| Influenza like illness       |                |                 |                 |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)            | 0              | 0               | 1               |
| Localised oedema             |                |                 |                 |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0               |
| Mucosal inflammation         |                |                 |                 |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)            | 0              | 0               | 1               |
| Malaise                      |                |                 |                 |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 1 / 11 (9.09%)  | 0 / 12 (0.00%)  |
| occurrences (all)            | 0              | 1               | 0               |
| Non-cardiac chest pain       |                |                 |                 |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)            | 0              | 0               | 1               |
| Oedema peripheral            |                |                 |                 |
| subjects affected / exposed  | 2 / 9 (22.22%) | 1 / 11 (9.09%)  | 2 / 12 (16.67%) |
| occurrences (all)            | 2              | 1               | 2               |
| Pain                         |                |                 |                 |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)            | 0              | 0               | 1               |
| Performance status decreased |                |                 |                 |
| subjects affected / exposed  | 1 / 9 (11.11%) | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)            | 1              | 0               | 0               |
| Peripheral swelling          |                |                 |                 |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0               |
| Pyrexia                      |                |                 |                 |
| subjects affected / exposed  | 3 / 9 (33.33%) | 4 / 11 (36.36%) | 5 / 12 (41.67%) |
| occurrences (all)            | 6              | 5               | 8               |
| Swelling face                |                |                 |                 |

|                                                                                                                          |                     |                      |                      |
|--------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|----------------------|
| subjects affected / exposed<br>occurrences (all)                                                                         | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Xerosis<br>subjects affected / exposed<br>occurrences (all)                                                              | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Temperature intolerance<br>subjects affected / exposed<br>occurrences (all)                                              | 0 / 9 (0.00%)<br>0  | 1 / 11 (9.09%)<br>1  | 0 / 12 (0.00%)<br>0  |
| Immune system disorders<br>Seasonal allergy<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Reproductive system and breast disorders<br>Heavy menstrual bleeding<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  |
| Breast pain<br>subjects affected / exposed<br>occurrences (all)                                                          | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Vulvovaginal pruritus<br>subjects affected / exposed<br>occurrences (all)                                                | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Respiratory, thoracic and mediastinal disorders<br>Apnoea<br>subjects affected / exposed<br>occurrences (all)            | 0 / 9 (0.00%)<br>0  | 1 / 11 (9.09%)<br>1  | 0 / 12 (0.00%)<br>0  |
| Cough<br>subjects affected / exposed<br>occurrences (all)                                                                | 1 / 9 (11.11%)<br>1 | 2 / 11 (18.18%)<br>3 | 2 / 12 (16.67%)<br>2 |
| Dysphonia<br>subjects affected / exposed<br>occurrences (all)                                                            | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Dyspnoea<br>subjects affected / exposed<br>occurrences (all)                                                             | 1 / 9 (11.11%)<br>1 | 1 / 11 (9.09%)<br>1  | 3 / 12 (25.00%)<br>3 |
| Nasal congestion                                                                                                         |                     |                      |                      |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)           | 0              | 0              | 1              |
| Hypoxia                     |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Haemoptysis                 |                |                |                |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)           | 1              | 0              | 1              |
| Oropharyngeal pain          |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Pleural effusion            |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Pneumonitis                 |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Pneumothorax                |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Pulmonary embolism          |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Rhinitis allergic           |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)           | 0              | 0              | 1              |
| Rhinorrhoea                 |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Upper-airway cough syndrome |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Wheezing                    |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Psychiatric disorders       |                |                |                |

|                                         |                |                |                 |
|-----------------------------------------|----------------|----------------|-----------------|
| Adjustment disorder with depressed mood |                |                |                 |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                       | 0              | 0              | 0               |
| Affective disorder                      |                |                |                 |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                       | 0              | 0              | 0               |
| Anxiety                                 |                |                |                 |
| subjects affected / exposed             | 1 / 9 (11.11%) | 1 / 11 (9.09%) | 3 / 12 (25.00%) |
| occurrences (all)                       | 1              | 1              | 3               |
| Depression                              |                |                |                 |
| subjects affected / exposed             | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 1 / 12 (8.33%)  |
| occurrences (all)                       | 1              | 0              | 1               |
| Disorientation                          |                |                |                 |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)                       | 0              | 1              | 0               |
| Insomnia                                |                |                |                 |
| subjects affected / exposed             | 2 / 9 (22.22%) | 0 / 11 (0.00%) | 2 / 12 (16.67%) |
| occurrences (all)                       | 2              | 0              | 2               |
| Libido decreased                        |                |                |                 |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                       | 0              | 0              | 0               |
| Mental status changes                   |                |                |                 |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)                       | 0              | 1              | 0               |
| Panic attack                            |                |                |                 |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)                       | 0              | 1              | 0               |
| Investigations                          |                |                |                 |
| Ammonia increased                       |                |                |                 |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)                       | 0              | 1              | 0               |
| Alanine aminotransferase increased      |                |                |                 |
| subjects affected / exposed             | 2 / 9 (22.22%) | 1 / 11 (9.09%) | 3 / 12 (25.00%) |
| occurrences (all)                       | 3              | 2              | 3               |
| Amylase increased                       |                |                |                 |

|                                        |                |                |                 |
|----------------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed            | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 2 / 12 (16.67%) |
| occurrences (all)                      | 0              | 1              | 3               |
| Blood albumin decreased                |                |                |                 |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                      | 0              | 0              | 0               |
| Aspartate aminotransferase increased   |                |                |                 |
| subjects affected / exposed            | 2 / 9 (22.22%) | 1 / 11 (9.09%) | 2 / 12 (16.67%) |
| occurrences (all)                      | 3              | 1              | 2               |
| Blood bilirubin increased              |                |                |                 |
| subjects affected / exposed            | 1 / 9 (11.11%) | 1 / 11 (9.09%) | 1 / 12 (8.33%)  |
| occurrences (all)                      | 1              | 1              | 1               |
| Blood alkaline phosphatase increased   |                |                |                 |
| subjects affected / exposed            | 3 / 9 (33.33%) | 1 / 11 (9.09%) | 2 / 12 (16.67%) |
| occurrences (all)                      | 3              | 1              | 2               |
| Blood calcium decreased                |                |                |                 |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                      | 0              | 0              | 0               |
| Blood calcium increased                |                |                |                 |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                      | 0              | 0              | 0               |
| Blood cholesterol increased            |                |                |                 |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                      | 0              | 0              | 0               |
| Blood creatine phosphokinase increased |                |                |                 |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                      | 0              | 0              | 0               |
| Blood creatinine increased             |                |                |                 |
| subjects affected / exposed            | 1 / 9 (11.11%) | 1 / 11 (9.09%) | 1 / 12 (8.33%)  |
| occurrences (all)                      | 2              | 1              | 1               |
| Blood glucose decreased                |                |                |                 |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                      | 0              | 0              | 0               |
| Blood lactic acid increased            |                |                |                 |

|                                             |               |                |                |
|---------------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                           | 0             | 0              | 0              |
| Blood glucose increased                     |               |                |                |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                           | 0             | 0              | 0              |
| Blood magnesium decreased                   |               |                |                |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                           | 0             | 0              | 0              |
| Blood phosphorus increased                  |               |                |                |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)                           | 0             | 0              | 1              |
| Blood potassium decreased                   |               |                |                |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                           | 0             | 0              | 0              |
| Blood prolactin increased                   |               |                |                |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)                           | 0             | 1              | 0              |
| Blood sodium decreased                      |               |                |                |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                           | 0             | 0              | 0              |
| Blood thyroid stimulating hormone decreased |               |                |                |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)                           | 0             | 0              | 1              |
| Blood thyroid stimulating hormone increased |               |                |                |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)                           | 0             | 0              | 1              |
| Blood uric acid increased                   |               |                |                |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)                           | 0             | 0              | 1              |
| C-reactive protein increased                |               |                |                |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                           | 0             | 0              | 0              |
| Cardiac murmur                              |               |                |                |

|                                          |                |                |                 |
|------------------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed              | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                        | 0              | 0              | 0               |
| Gamma-glutamyltransferase increased      |                |                |                 |
| subjects affected / exposed              | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                        | 1              | 0              | 0               |
| Haemoglobin decreased                    |                |                |                 |
| subjects affected / exposed              | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                        | 0              | 0              | 0               |
| International normalised ratio increased |                |                |                 |
| subjects affected / exposed              | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 1 / 12 (8.33%)  |
| occurrences (all)                        | 0              | 0              | 1               |
| Lipase increased                         |                |                |                 |
| subjects affected / exposed              | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 3 / 12 (25.00%) |
| occurrences (all)                        | 1              | 0              | 4               |
| Liver function test increased            |                |                |                 |
| subjects affected / exposed              | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                        | 0              | 0              | 0               |
| Neutrophil count decreased               |                |                |                 |
| subjects affected / exposed              | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)                        | 0              | 1              | 0               |
| Platelet count decreased                 |                |                |                 |
| subjects affected / exposed              | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)                        | 0              | 2              | 0               |
| Troponin I increased                     |                |                |                 |
| subjects affected / exposed              | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)                        | 0              | 1              | 0               |
| Transaminases increased                  |                |                |                 |
| subjects affected / exposed              | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                        | 0              | 0              | 0               |
| Troponin increased                       |                |                |                 |
| subjects affected / exposed              | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                        | 0              | 0              | 0               |
| Urine phosphorus increased               |                |                |                 |

|                                                |                |                 |                 |
|------------------------------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                              | 0              | 0               | 0               |
| Urine calcium increased                        |                |                 |                 |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                              | 0              | 0               | 0               |
| Weight decreased                               |                |                 |                 |
| subjects affected / exposed                    | 2 / 9 (22.22%) | 0 / 11 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)                              | 2              | 0               | 1               |
| White blood cell count decreased               |                |                 |                 |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                              | 0              | 0               | 0               |
| White blood cell count increased               |                |                 |                 |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                              | 0              | 0               | 0               |
| Injury, poisoning and procedural complications |                |                 |                 |
| Fall                                           |                |                 |                 |
| subjects affected / exposed                    | 1 / 9 (11.11%) | 1 / 11 (9.09%)  | 2 / 12 (16.67%) |
| occurrences (all)                              | 1              | 1               | 2               |
| Femur fracture                                 |                |                 |                 |
| subjects affected / exposed                    | 1 / 9 (11.11%) | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                              | 1              | 0               | 0               |
| Infusion related reaction                      |                |                 |                 |
| subjects affected / exposed                    | 1 / 9 (11.11%) | 2 / 11 (18.18%) | 0 / 12 (0.00%)  |
| occurrences (all)                              | 1              | 2               | 0               |
| Muscle strain                                  |                |                 |                 |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 1 / 11 (9.09%)  | 0 / 12 (0.00%)  |
| occurrences (all)                              | 0              | 1               | 0               |
| Lip injury                                     |                |                 |                 |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 1 / 11 (9.09%)  | 0 / 12 (0.00%)  |
| occurrences (all)                              | 0              | 1               | 0               |
| Procedural pain                                |                |                 |                 |
| subjects affected / exposed                    | 1 / 9 (11.11%) | 1 / 11 (9.09%)  | 0 / 12 (0.00%)  |
| occurrences (all)                              | 1              | 1               | 0               |
| Rib fracture                                   |                |                 |                 |

|                               |                |                |                |
|-------------------------------|----------------|----------------|----------------|
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)             | 0              | 0              | 1              |
| Skin abrasion                 |                |                |                |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)             | 0              | 1              | 0              |
| Tooth fracture                |                |                |                |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)             | 0              | 1              | 0              |
| Vascular access site erythema |                |                |                |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)             | 0              | 0              | 0              |
| Wound secretion               |                |                |                |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)             | 0              | 0              | 0              |
| Cardiac disorders             |                |                |                |
| Atrial fibrillation           |                |                |                |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)             | 0              | 0              | 0              |
| Palpitations                  |                |                |                |
| subjects affected / exposed   | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)             | 1              | 0              | 0              |
| Pericardial effusion          |                |                |                |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)             | 0              | 0              | 0              |
| Sinus bradycardia             |                |                |                |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)             | 0              | 0              | 0              |
| Sinus tachycardia             |                |                |                |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)             | 0              | 0              | 0              |
| Tachycardia                   |                |                |                |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)             | 0              | 0              | 1              |
| Nervous system disorders      |                |                |                |
| Aphasia                       |                |                |                |

|                               |                |                |                 |
|-------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 1 / 12 (8.33%)  |
| occurrences (all)             | 0              | 0              | 1               |
| Cognitive disorder            |                |                |                 |
| subjects affected / exposed   | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)             | 1              | 0              | 0               |
| Dysarthria                    |                |                |                 |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)             | 0              | 1              | 0               |
| Dizziness                     |                |                |                 |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 2 / 12 (16.67%) |
| occurrences (all)             | 0              | 0              | 3               |
| Headache                      |                |                |                 |
| subjects affected / exposed   | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 1 / 12 (8.33%)  |
| occurrences (all)             | 1              | 0              | 1               |
| Dysgeusia                     |                |                |                 |
| subjects affected / exposed   | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)             | 1              | 0              | 0               |
| Hyperaesthesia                |                |                |                 |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)             | 0              | 1              | 0               |
| Lethargy                      |                |                |                 |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0               |
| Neuralgia                     |                |                |                 |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0               |
| Neuropathy peripheral         |                |                |                 |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0               |
| Paraesthesia                  |                |                |                 |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0               |
| Parkinson's disease           |                |                |                 |
| subjects affected / exposed   | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0               |
| Peripheral sensory neuropathy |                |                |                 |

|                                      |                |                |                 |
|--------------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed          | 2 / 9 (22.22%) | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                    | 2              | 0              | 0               |
| Peripheral motor neuropathy          |                |                |                 |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 1              | 0               |
| Post herpetic neuralgia              |                |                |                 |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |
| Restless legs syndrome               |                |                |                 |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 1 / 12 (8.33%)  |
| occurrences (all)                    | 0              | 0              | 1               |
| Radiculopathy                        |                |                |                 |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 1              | 0               |
| Somnolence                           |                |                |                 |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 1              | 0               |
| Sciatica                             |                |                |                 |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 1 / 12 (8.33%)  |
| occurrences (all)                    | 0              | 0              | 1               |
| Tension headache                     |                |                |                 |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 1              | 0               |
| Tremor                               |                |                |                 |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |
| Blood and lymphatic system disorders |                |                |                 |
| Anaemia                              |                |                |                 |
| subjects affected / exposed          | 3 / 9 (33.33%) | 1 / 11 (9.09%) | 6 / 12 (50.00%) |
| occurrences (all)                    | 4              | 1              | 6               |
| Eosinophilia                         |                |                |                 |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |
| Iron deficiency anaemia              |                |                |                 |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 0              | 0               |

|                             |               |                |                |
|-----------------------------|---------------|----------------|----------------|
| Leukocytosis                |               |                |                |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Lymphopenia                 |               |                |                |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Thrombocytopenia            |               |                |                |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Neutropenia                 |               |                |                |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Ear and labyrinth disorders |               |                |                |
| Ear pain                    |               |                |                |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 11 (9.09%) | 1 / 12 (8.33%) |
| occurrences (all)           | 0             | 1              | 1              |
| Hypoacusis                  |               |                |                |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0             | 1              | 0              |
| Vertigo                     |               |                |                |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Eye disorders               |               |                |                |
| Dry eye                     |               |                |                |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Iridocyclitis               |               |                |                |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0             | 1              | 0              |
| Eyelid irritation           |               |                |                |
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Vision blurred              |               |                |                |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0             | 1              | 0              |
| Swelling of eyelid          |               |                |                |

|                                                  |                    |                     |                     |
|--------------------------------------------------|--------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | 1 / 11 (9.09%)<br>1 | 0 / 12 (0.00%)<br>0 |
| Gastrointestinal disorders                       |                    |                     |                     |
| Abdominal discomfort                             |                    |                     |                     |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 11 (0.00%)      | 1 / 12 (8.33%)      |
| occurrences (all)                                | 0                  | 0                   | 1                   |
| Abdominal distension                             |                    |                     |                     |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 1 / 11 (9.09%)      | 1 / 12 (8.33%)      |
| occurrences (all)                                | 0                  | 1                   | 1                   |
| Abdominal pain                                   |                    |                     |                     |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 1 / 11 (9.09%)      | 5 / 12 (41.67%)     |
| occurrences (all)                                | 0                  | 1                   | 8                   |
| Abdominal pain lower                             |                    |                     |                     |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 11 (0.00%)      | 0 / 12 (0.00%)      |
| occurrences (all)                                | 0                  | 0                   | 0                   |
| Abdominal pain upper                             |                    |                     |                     |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 11 (0.00%)      | 1 / 12 (8.33%)      |
| occurrences (all)                                | 0                  | 0                   | 1                   |
| Ascites                                          |                    |                     |                     |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 11 (0.00%)      | 0 / 12 (0.00%)      |
| occurrences (all)                                | 0                  | 0                   | 0                   |
| Colitis                                          |                    |                     |                     |
| subjects affected / exposed                      | 1 / 9 (11.11%)     | 0 / 11 (0.00%)      | 1 / 12 (8.33%)      |
| occurrences (all)                                | 2                  | 0                   | 1                   |
| Constipation                                     |                    |                     |                     |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 2 / 11 (18.18%)     | 3 / 12 (25.00%)     |
| occurrences (all)                                | 0                  | 2                   | 3                   |
| Diarrhoea                                        |                    |                     |                     |
| subjects affected / exposed                      | 3 / 9 (33.33%)     | 1 / 11 (9.09%)      | 6 / 12 (50.00%)     |
| occurrences (all)                                | 6                  | 1                   | 12                  |
| Dyspepsia                                        |                    |                     |                     |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 1 / 11 (9.09%)      | 0 / 12 (0.00%)      |
| occurrences (all)                                | 0                  | 1                   | 0                   |
| Dry mouth                                        |                    |                     |                     |
| subjects affected / exposed                      | 1 / 9 (11.11%)     | 1 / 11 (9.09%)      | 0 / 12 (0.00%)      |
| occurrences (all)                                | 1                  | 1                   | 0                   |

|                                    |                |                 |                 |
|------------------------------------|----------------|-----------------|-----------------|
| Dysphagia                          |                |                 |                 |
| subjects affected / exposed        | 1 / 9 (11.11%) | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                  | 1              | 0               | 0               |
| Enteritis                          |                |                 |                 |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Flatulence                         |                |                 |                 |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Frequent bowel movements           |                |                 |                 |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Gastritis                          |                |                 |                 |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Gastrointestinal motility disorder |                |                 |                 |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)                  | 0              | 0               | 1               |
| Gastrointestinal haemorrhage       |                |                 |                 |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Gastrooesophageal reflux disease   |                |                 |                 |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Immune-mediated enterocolitis      |                |                 |                 |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Impaired gastric emptying          |                |                 |                 |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Mouth ulceration                   |                |                 |                 |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Nausea                             |                |                 |                 |
| subjects affected / exposed        | 2 / 9 (22.22%) | 3 / 11 (27.27%) | 6 / 12 (50.00%) |
| occurrences (all)                  | 2              | 3               | 12              |

|                                                                                     |                     |                     |                      |
|-------------------------------------------------------------------------------------|---------------------|---------------------|----------------------|
| Oesophageal varices haemorrhage<br>subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>1 | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Oral dysaesthesia<br>subjects affected / exposed<br>occurrences (all)               | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Proctalgia<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Rectal haemorrhage<br>subjects affected / exposed<br>occurrences (all)              | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Stomatitis<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)                        | 1 / 9 (11.11%)<br>1 | 1 / 11 (9.09%)<br>1 | 4 / 12 (33.33%)<br>6 |
| Hepatobiliary disorders                                                             |                     |                     |                      |
| Biliary obstruction<br>subjects affected / exposed<br>occurrences (all)             | 1 / 9 (11.11%)<br>1 | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Autoimmune hepatitis<br>subjects affected / exposed<br>occurrences (all)            | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Hepatitis<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Hepatic failure<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Hyperbilirubinaemia<br>subjects affected / exposed<br>occurrences (all)             | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Hypertransaminasaemia                                                               |                     |                     |                      |

|                                        |                |                |                |
|----------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Immune-mediated hepatitis              |                |                |                |
| subjects affected / exposed            | 1 / 9 (11.11%) | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)                      | 1              | 1              | 0              |
| Jaundice cholestatic                   |                |                |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Portal hypertension                    |                |                |                |
| subjects affected / exposed            | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                      | 1              | 0              | 0              |
| Skin and subcutaneous tissue disorders |                |                |                |
| Alopecia                               |                |                |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Acquired porokeratosis                 |                |                |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Dermatitis acneiform                   |                |                |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Drug eruption                          |                |                |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Dry skin                               |                |                |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)                      | 0              | 1              | 0              |
| Eczema                                 |                |                |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Erythema                               |                |                |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Ecchymosis                             |                |                |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |

|                                            |               |                |                 |
|--------------------------------------------|---------------|----------------|-----------------|
| Night sweats                               |               |                |                 |
| subjects affected / exposed                | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                          | 0             | 0              | 0               |
| Keloid scar                                |               |                |                 |
| subjects affected / exposed                | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                          | 0             | 0              | 0               |
| Leukoplakia                                |               |                |                 |
| subjects affected / exposed                | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%)  |
| occurrences (all)                          | 0             | 0              | 1               |
| Rash                                       |               |                |                 |
| subjects affected / exposed                | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 3 / 12 (25.00%) |
| occurrences (all)                          | 0             | 0              | 3               |
| Pruritus                                   |               |                |                 |
| subjects affected / exposed                | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 1 / 12 (8.33%)  |
| occurrences (all)                          | 0             | 0              | 1               |
| Palmar-plantar erythrodysesthesia syndrome |               |                |                 |
| subjects affected / exposed                | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                          | 0             | 0              | 0               |
| Rash maculo-papular                        |               |                |                 |
| subjects affected / exposed                | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                          | 0             | 0              | 0               |
| Rash macular                               |               |                |                 |
| subjects affected / exposed                | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                          | 0             | 0              | 0               |
| Rash erythematous                          |               |                |                 |
| subjects affected / exposed                | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                          | 0             | 0              | 0               |
| Rash pruritic                              |               |                |                 |
| subjects affected / exposed                | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                          | 0             | 0              | 0               |
| Rash vesicular                             |               |                |                 |
| subjects affected / exposed                | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                          | 0             | 0              | 0               |
| Transient acantholytic dermatosis          |               |                |                 |

|                                                                                  |                     |                     |                     |
|----------------------------------------------------------------------------------|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                                 | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0 |
| Skin hypopigmentation<br>subjects affected / exposed<br>occurrences (all)        | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0 |
| Urticaria<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0 |
| Vitiligo<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0 |
| Renal and urinary disorders                                                      |                     |                     |                     |
| Acute kidney injury<br>subjects affected / exposed<br>occurrences (all)          | 1 / 9 (11.11%)<br>1 | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0 |
| Pollakiuria<br>subjects affected / exposed<br>occurrences (all)                  | 1 / 9 (11.11%)<br>1 | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0 |
| Proteinuria<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 1 / 12 (8.33%)<br>1 |
| Haematuria<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 9 (0.00%)<br>0  | 1 / 11 (9.09%)<br>1 | 1 / 12 (8.33%)<br>1 |
| Tubulointerstitial nephritis<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0 |
| Endocrine disorders                                                              |                     |                     |                     |
| Adrenal insufficiency<br>subjects affected / exposed<br>occurrences (all)        | 1 / 9 (11.11%)<br>1 | 1 / 11 (9.09%)<br>1 | 1 / 12 (8.33%)<br>2 |
| Autoimmune thyroiditis<br>subjects affected / exposed<br>occurrences (all)       | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 | 1 / 12 (8.33%)<br>1 |
| Hyperthyroidism                                                                  |                     |                     |                     |

|                                                 |                |                 |                |
|-------------------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed                     | 2 / 9 (22.22%) | 1 / 11 (9.09%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 2              | 1               | 0              |
| Hypophysitis                                    |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 0              | 0               | 0              |
| Hypopituitarism                                 |                |                 |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 1              | 0               | 0              |
| Hypothyroidism                                  |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 11 (9.09%)  | 1 / 12 (8.33%) |
| occurrences (all)                               | 0              | 1               | 1              |
| Thyroiditis                                     |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 0              | 0               | 0              |
| Inappropriate antidiuretic hormone secretion    |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 11 (9.09%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 0              | 1               | 0              |
| Musculoskeletal and connective tissue disorders |                |                 |                |
| Arthralgia                                      |                |                 |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 3 / 11 (27.27%) | 1 / 12 (8.33%) |
| occurrences (all)                               | 1              | 3               | 1              |
| Back pain                                       |                |                 |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 1 / 11 (9.09%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 1              | 1               | 0              |
| Groin pain                                      |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 0              | 0               | 0              |
| Hypercreatinaemia                               |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 0              | 0               | 0              |
| Joint swelling                                  |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 1 / 12 (8.33%) |
| occurrences (all)                               | 0              | 0               | 1              |
| Muscular weakness                               |                |                 |                |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 1 / 12 (8.33%) |
| occurrences (all)           | 0              | 1              | 1              |
| Muscle spasms               |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Musculoskeletal chest pain  |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Myalgia                     |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)           | 0              | 0              | 1              |
| Myositis                    |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Neck pain                   |                |                |                |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Pain in extremity           |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Sacral pain                 |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Infections and infestations |                |                |                |
| Bronchitis                  |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Campylobacter infection     |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| COVID-19                    |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Candida infection           |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| Cellulitis                  |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Conjunctivitis              |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Cystitis                    |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Diverticulitis              |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Eye infection bacterial     |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Folliculitis                |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Gastroenteritis             |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Hepatitis viral             |                |                |                |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Gastrointestinal infection  |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Herpes zoster               |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)           | 0              | 0              | 1              |
| Hordeolum                   |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Influenza                   |                |                |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 11 (9.09%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 2              | 0              |

|                                   |                |                 |                |
|-----------------------------------|----------------|-----------------|----------------|
| Localised infection               |                |                 |                |
| subjects affected / exposed       | 1 / 9 (11.11%) | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                 | 1              | 0               | 0              |
| Mucosal infection                 |                |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0              |
| Nasopharyngitis                   |                |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0              |
| Oral candidiasis                  |                |                 |                |
| subjects affected / exposed       | 1 / 9 (11.11%) | 2 / 11 (18.18%) | 0 / 12 (0.00%) |
| occurrences (all)                 | 1              | 2               | 0              |
| Norovirus infection               |                |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0              |
| Pharyngitis                       |                |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%)  | 1 / 11 (9.09%)  | 0 / 12 (0.00%) |
| occurrences (all)                 | 0              | 1               | 0              |
| Rash pustular                     |                |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0              |
| Pneumonia                         |                |                 |                |
| subjects affected / exposed       | 1 / 9 (11.11%) | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                 | 1              | 0               | 0              |
| Soft tissue infection             |                |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0              |
| Skin infection                    |                |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%)  | 1 / 11 (9.09%)  | 0 / 12 (0.00%) |
| occurrences (all)                 | 0              | 1               | 0              |
| Spontaneous bacterial peritonitis |                |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                 | 0              | 0               | 0              |
| Upper respiratory tract infection |                |                 |                |
| subjects affected / exposed       | 1 / 9 (11.11%) | 1 / 11 (9.09%)  | 1 / 12 (8.33%) |
| occurrences (all)                 | 3              | 1               | 1              |

|                                                                                    |                     |                      |                      |
|------------------------------------------------------------------------------------|---------------------|----------------------|----------------------|
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)        | 0 / 9 (0.00%)<br>0  | 2 / 11 (18.18%)<br>2 | 3 / 12 (25.00%)<br>3 |
| Staphylococcal infection<br>subjects affected / exposed<br>occurrences (all)       | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Vascular access site infection<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0  | 1 / 11 (9.09%)<br>1  | 0 / 12 (0.00%)<br>0  |
| Viral infection<br>subjects affected / exposed<br>occurrences (all)                | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Metabolism and nutrition disorders                                                 |                     |                      |                      |
| Decreased appetite<br>subjects affected / exposed<br>occurrences (all)             | 1 / 9 (11.11%)<br>1 | 5 / 11 (45.45%)<br>5 | 3 / 12 (25.00%)<br>3 |
| Dehydration<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 9 (0.00%)<br>0  | 1 / 11 (9.09%)<br>1  | 4 / 12 (33.33%)<br>5 |
| Electrolyte imbalance<br>subjects affected / exposed<br>occurrences (all)          | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Hyperglycaemia<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 9 (11.11%)<br>1 | 1 / 11 (9.09%)<br>1  | 0 / 12 (0.00%)<br>0  |
| Hypercalcaemia<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 9 (0.00%)<br>0  | 1 / 11 (9.09%)<br>1  | 0 / 12 (0.00%)<br>0  |
| Hyperkalaemia<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0  | 2 / 12 (16.67%)<br>3 |
| Hypermagnesaemia<br>subjects affected / exposed<br>occurrences (all)               | 0 / 9 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Hyperlipasaemia                                                                    |                     |                      |                      |

|                             |                |                 |                 |
|-----------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Hyperuricaemia              |                |                 |                 |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 2              | 0               | 0               |
| Hypernatraemia              |                |                 |                 |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Hypoalbuminaemia            |                |                 |                 |
| subjects affected / exposed | 1 / 9 (11.11%) | 1 / 11 (9.09%)  | 5 / 12 (41.67%) |
| occurrences (all)           | 1              | 1               | 5               |
| Hypocalcaemia               |                |                 |                 |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 2 / 12 (16.67%) |
| occurrences (all)           | 0              | 0               | 3               |
| Hypochloraemia              |                |                 |                 |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Hypokalaemia                |                |                 |                 |
| subjects affected / exposed | 3 / 9 (33.33%) | 0 / 11 (0.00%)  | 2 / 12 (16.67%) |
| occurrences (all)           | 4              | 0               | 4               |
| Hypomagnesaemia             |                |                 |                 |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)           | 0              | 0               | 1               |
| Hyponatraemia               |                |                 |                 |
| subjects affected / exposed | 0 / 9 (0.00%)  | 3 / 11 (27.27%) | 3 / 12 (25.00%) |
| occurrences (all)           | 0              | 6               | 5               |
| Hypovolaemia                |                |                 |                 |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Hypophosphataemia           |                |                 |                 |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 11 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)           | 1              | 0               | 1               |
| Iron deficiency             |                |                 |                 |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 11 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Malnutrition                |                |                 |                 |

|                             |               |                |                |
|-----------------------------|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 0 / 11 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |

| <b>Non-serious adverse events</b>                                   | Part 1B: BMS-986249 1200mg Q8W+ Nivolumab Combination | Part 1B: BMS-986249 1600mg Q8W+ Nivolumab Combination | Part 2A: Melanoma Arms BMS-986249 240mg IV Q3W |
|---------------------------------------------------------------------|-------------------------------------------------------|-------------------------------------------------------|------------------------------------------------|
| Total subjects affected by non-serious adverse events               |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 9 / 9 (100.00%)                                       | 10 / 10 (100.00%)                                     | 3 / 3 (100.00%)                                |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                                       |                                                       |                                                |
| Acrochordon                                                         |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                         | 0 / 10 (0.00%)                                        | 0 / 3 (0.00%)                                  |
| occurrences (all)                                                   | 0                                                     | 0                                                     | 0                                              |
| Malignant neoplasm progression                                      |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                         | 0 / 10 (0.00%)                                        | 0 / 3 (0.00%)                                  |
| occurrences (all)                                                   | 0                                                     | 0                                                     | 0                                              |
| Cancer pain                                                         |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                         | 0 / 10 (0.00%)                                        | 0 / 3 (0.00%)                                  |
| occurrences (all)                                                   | 0                                                     | 0                                                     | 0                                              |
| Tumour pain                                                         |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 2 / 9 (22.22%)                                        | 0 / 10 (0.00%)                                        | 0 / 3 (0.00%)                                  |
| occurrences (all)                                                   | 2                                                     | 0                                                     | 0                                              |
| Metastases to central nervous system                                |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                         | 0 / 10 (0.00%)                                        | 0 / 3 (0.00%)                                  |
| occurrences (all)                                                   | 0                                                     | 0                                                     | 0                                              |
| Vascular disorders                                                  |                                                       |                                                       |                                                |
| Deep vein thrombosis                                                |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                         | 0 / 10 (0.00%)                                        | 0 / 3 (0.00%)                                  |
| occurrences (all)                                                   | 0                                                     | 0                                                     | 0                                              |
| Haematoma                                                           |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                         | 0 / 10 (0.00%)                                        | 0 / 3 (0.00%)                                  |
| occurrences (all)                                                   | 0                                                     | 0                                                     | 0                                              |
| Haemorrhage                                                         |                                                       |                                                       |                                                |
| subjects affected / exposed                                         | 0 / 9 (0.00%)                                         | 0 / 10 (0.00%)                                        | 0 / 3 (0.00%)                                  |
| occurrences (all)                                                   | 0                                                     | 0                                                     | 0                                              |
| Hot flush                                                           |                                                       |                                                       |                                                |

|                                                      |                |                 |               |
|------------------------------------------------------|----------------|-----------------|---------------|
| subjects affected / exposed                          | 1 / 9 (11.11%) | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)                                    | 2              | 1               | 0             |
| Hypertension                                         |                |                 |               |
| subjects affected / exposed                          | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                                    | 1              | 0               | 0             |
| Hypotension                                          |                |                 |               |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)                                    | 0              | 1               | 0             |
| Pallor                                               |                |                 |               |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                                    | 0              | 0               | 0             |
| Venous thrombosis                                    |                |                 |               |
| subjects affected / exposed                          | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                                    | 1              | 0               | 0             |
| General disorders and administration site conditions |                |                 |               |
| Asthenia                                             |                |                 |               |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)                                    | 0              | 1               | 0             |
| Application site reaction                            |                |                 |               |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                                    | 0              | 0               | 0             |
| Axillary pain                                        |                |                 |               |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                                    | 0              | 0               | 0             |
| Chest discomfort                                     |                |                 |               |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                                    | 0              | 0               | 0             |
| Chest pain                                           |                |                 |               |
| subjects affected / exposed                          | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                                    | 1              | 0               | 0             |
| Chills                                               |                |                 |               |
| subjects affected / exposed                          | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                                    | 0              | 0               | 0             |
| Complication associated with device                  |                |                 |               |

|                              |                |                 |                |
|------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Device related thrombosis    |                |                 |                |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Gait disturbance             |                |                 |                |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Fatigue                      |                |                 |                |
| subjects affected / exposed  | 6 / 9 (66.67%) | 5 / 10 (50.00%) | 0 / 3 (0.00%)  |
| occurrences (all)            | 8              | 6               | 0              |
| Hernia pain                  |                |                 |                |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 1 / 3 (33.33%) |
| occurrences (all)            | 0              | 0               | 1              |
| Injection site extravasation |                |                 |                |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Influenza like illness       |                |                 |                |
| subjects affected / exposed  | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)            | 1              | 0               | 0              |
| Localised oedema             |                |                 |                |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 1 / 3 (33.33%) |
| occurrences (all)            | 0              | 0               | 1              |
| Mucosal inflammation         |                |                 |                |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Malaise                      |                |                 |                |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Non-cardiac chest pain       |                |                 |                |
| subjects affected / exposed  | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Oedema peripheral            |                |                 |                |
| subjects affected / exposed  | 4 / 9 (44.44%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)            | 4              | 0               | 0              |
| Pain                         |                |                 |                |

|                                                                                                                          |                     |                      |                     |
|--------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                                                                         | 0 / 9 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Performance status decreased<br>subjects affected / exposed<br>occurrences (all)                                         | 0 / 9 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Peripheral swelling<br>subjects affected / exposed<br>occurrences (all)                                                  | 0 / 9 (0.00%)<br>0  | 1 / 10 (10.00%)<br>1 | 0 / 3 (0.00%)<br>0  |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)                                                              | 1 / 9 (11.11%)<br>1 | 1 / 10 (10.00%)<br>1 | 1 / 3 (33.33%)<br>1 |
| Swelling face<br>subjects affected / exposed<br>occurrences (all)                                                        | 0 / 9 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Xerosis<br>subjects affected / exposed<br>occurrences (all)                                                              | 0 / 9 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Temperature intolerance<br>subjects affected / exposed<br>occurrences (all)                                              | 0 / 9 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Immune system disorders<br>Seasonal allergy<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 9 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Reproductive system and breast disorders<br>Heavy menstrual bleeding<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Breast pain<br>subjects affected / exposed<br>occurrences (all)                                                          | 0 / 9 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Vulvovaginal pruritus<br>subjects affected / exposed<br>occurrences (all)                                                | 0 / 9 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Respiratory, thoracic and mediastinal disorders                                                                          |                     |                      |                     |

|                             |                |                 |               |
|-----------------------------|----------------|-----------------|---------------|
| Apnoea                      |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Cough                       |                |                 |               |
| subjects affected / exposed | 1 / 9 (11.11%) | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 1              | 1               | 0             |
| Dysphonia                   |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Dyspnoea                    |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Nasal congestion            |                |                 |               |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 1              | 0               | 0             |
| Hypoxia                     |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 1               | 0             |
| Haemoptysis                 |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Oropharyngeal pain          |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Pleural effusion            |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Pneumonitis                 |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Pneumothorax                |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Pulmonary embolism          |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |

|                                         |                |                 |               |
|-----------------------------------------|----------------|-----------------|---------------|
| Rhinitis allergic                       |                |                 |               |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                       | 0              | 0               | 0             |
| Rhinorrhoea                             |                |                 |               |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                       | 0              | 0               | 0             |
| Upper-airway cough syndrome             |                |                 |               |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                       | 0              | 0               | 0             |
| Wheezing                                |                |                 |               |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                       | 0              | 0               | 0             |
| Psychiatric disorders                   |                |                 |               |
| Adjustment disorder with depressed mood |                |                 |               |
| subjects affected / exposed             | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                       | 1              | 0               | 0             |
| Affective disorder                      |                |                 |               |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                       | 0              | 0               | 0             |
| Anxiety                                 |                |                 |               |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                       | 0              | 0               | 0             |
| Depression                              |                |                 |               |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                       | 0              | 0               | 0             |
| Disorientation                          |                |                 |               |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                       | 0              | 0               | 0             |
| Insomnia                                |                |                 |               |
| subjects affected / exposed             | 2 / 9 (22.22%) | 2 / 10 (20.00%) | 0 / 3 (0.00%) |
| occurrences (all)                       | 2              | 2               | 0             |
| Libido decreased                        |                |                 |               |
| subjects affected / exposed             | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                       | 0              | 0               | 0             |
| Mental status changes                   |                |                 |               |

|                                      |                |                 |               |
|--------------------------------------|----------------|-----------------|---------------|
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                    | 0              | 0               | 0             |
| Panic attack                         |                |                 |               |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                    | 0              | 0               | 0             |
| Investigations                       |                |                 |               |
| Ammonia increased                    |                |                 |               |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                    | 0              | 0               | 0             |
| Alanine aminotransferase increased   |                |                 |               |
| subjects affected / exposed          | 2 / 9 (22.22%) | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)                    | 3              | 2               | 0             |
| Amylase increased                    |                |                 |               |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                    | 0              | 0               | 0             |
| Blood albumin decreased              |                |                 |               |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                    | 0              | 0               | 0             |
| Aspartate aminotransferase increased |                |                 |               |
| subjects affected / exposed          | 3 / 9 (33.33%) | 2 / 10 (20.00%) | 0 / 3 (0.00%) |
| occurrences (all)                    | 5              | 3               | 0             |
| Blood bilirubin increased            |                |                 |               |
| subjects affected / exposed          | 1 / 9 (11.11%) | 2 / 10 (20.00%) | 0 / 3 (0.00%) |
| occurrences (all)                    | 1              | 2               | 0             |
| Blood alkaline phosphatase increased |                |                 |               |
| subjects affected / exposed          | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                    | 1              | 0               | 0             |
| Blood calcium decreased              |                |                 |               |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                    | 0              | 0               | 0             |
| Blood calcium increased              |                |                 |               |
| subjects affected / exposed          | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                    | 0              | 0               | 0             |
| Blood cholesterol increased          |                |                 |               |

|                                             |               |                 |               |
|---------------------------------------------|---------------|-----------------|---------------|
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Blood creatine phosphokinase increased      |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Blood creatinine increased                  |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 1               | 0             |
| Blood glucose decreased                     |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Blood lactic acid increased                 |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Blood glucose increased                     |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Blood magnesium decreased                   |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Blood phosphorus increased                  |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Blood potassium decreased                   |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Blood prolactin increased                   |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Blood sodium decreased                      |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Blood thyroid stimulating hormone decreased |               |                 |               |

|                                             |               |                 |               |
|---------------------------------------------|---------------|-----------------|---------------|
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Blood thyroid stimulating hormone increased |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Blood uric acid increased                   |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| C-reactive protein increased                |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Cardiac murmur                              |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 1               | 0             |
| Gamma-glutamyltransferase increased         |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 1               | 0             |
| Haemoglobin decreased                       |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| International normalised ratio increased    |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Lipase increased                            |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 1               | 0             |
| Liver function test increased               |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Neutrophil count decreased                  |               |                 |               |
| subjects affected / exposed                 | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                           | 0             | 0               | 0             |
| Platelet count decreased                    |               |                 |               |

|                                                |                |                 |                |
|------------------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                              | 0              | 0               | 0              |
| Troponin I increased                           |                |                 |                |
| subjects affected / exposed                    | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                              | 2              | 0               | 0              |
| Transaminases increased                        |                |                 |                |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                              | 0              | 0               | 0              |
| Troponin increased                             |                |                 |                |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                              | 0              | 0               | 0              |
| Urine phosphorus increased                     |                |                 |                |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 1 / 3 (33.33%) |
| occurrences (all)                              | 0              | 0               | 1              |
| Urine calcium increased                        |                |                 |                |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 1 / 3 (33.33%) |
| occurrences (all)                              | 0              | 0               | 1              |
| Weight decreased                               |                |                 |                |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)                              | 0              | 1               | 0              |
| White blood cell count decreased               |                |                 |                |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)                              | 0              | 1               | 0              |
| White blood cell count increased               |                |                 |                |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                              | 0              | 0               | 0              |
| Injury, poisoning and procedural complications |                |                 |                |
| Fall                                           |                |                 |                |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                              | 0              | 0               | 0              |
| Femur fracture                                 |                |                 |                |
| subjects affected / exposed                    | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                              | 0              | 0               | 0              |
| Infusion related reaction                      |                |                 |                |

|                               |               |                 |               |
|-------------------------------|---------------|-----------------|---------------|
| subjects affected / exposed   | 0 / 9 (0.00%) | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 1               | 0             |
| Muscle strain                 |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Lip injury                    |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Procedural pain               |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Rib fracture                  |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Skin abrasion                 |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Tooth fracture                |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Vascular access site erythema |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Wound secretion               |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Cardiac disorders             |               |                 |               |
| Atrial fibrillation           |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Palpitations                  |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Pericardial effusion          |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |

|                             |                |                 |                |
|-----------------------------|----------------|-----------------|----------------|
| Sinus bradycardia           |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Sinus tachycardia           |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Tachycardia                 |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 1 / 3 (33.33%) |
| occurrences (all)           | 0              | 0               | 1              |
| Nervous system disorders    |                |                 |                |
| Aphasia                     |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Cognitive disorder          |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0              |
| Dysarthria                  |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Dizziness                   |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0              |
| Headache                    |                |                 |                |
| subjects affected / exposed | 4 / 9 (44.44%) | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)           | 5              | 1               | 0              |
| Dysgeusia                   |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Hyperaesthesia              |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Lethargy                    |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Neuralgia                   |                |                 |                |

|                               |               |                 |               |
|-------------------------------|---------------|-----------------|---------------|
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Neuropathy peripheral         |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Paraesthesia                  |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 1               | 0             |
| Parkinson's disease           |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Peripheral sensory neuropathy |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Peripheral motor neuropathy   |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Post herpetic neuralgia       |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Restless legs syndrome        |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Radiculopathy                 |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Somnolence                    |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Sciatica                      |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Tension headache              |               |                 |               |
| subjects affected / exposed   | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)             | 0             | 0               | 0             |
| Tremor                        |               |                 |               |

|                                                  |                    |                     |                    |
|--------------------------------------------------|--------------------|---------------------|--------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0 | 0 / 3 (0.00%)<br>0 |
| Blood and lymphatic system disorders             |                    |                     |                    |
| Anaemia                                          |                    |                     |                    |
| subjects affected / exposed                      | 1 / 9 (11.11%)     | 4 / 10 (40.00%)     | 1 / 3 (33.33%)     |
| occurrences (all)                                | 1                  | 4                   | 1                  |
| Eosinophilia                                     |                    |                     |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      |
| occurrences (all)                                | 0                  | 0                   | 0                  |
| Iron deficiency anaemia                          |                    |                     |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      |
| occurrences (all)                                | 0                  | 0                   | 0                  |
| Leukocytosis                                     |                    |                     |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      |
| occurrences (all)                                | 0                  | 0                   | 0                  |
| Lymphopenia                                      |                    |                     |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      |
| occurrences (all)                                | 0                  | 0                   | 0                  |
| Thrombocytopenia                                 |                    |                     |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      |
| occurrences (all)                                | 0                  | 0                   | 0                  |
| Neutropenia                                      |                    |                     |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      |
| occurrences (all)                                | 0                  | 0                   | 0                  |
| Ear and labyrinth disorders                      |                    |                     |                    |
| Ear pain                                         |                    |                     |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      |
| occurrences (all)                                | 0                  | 0                   | 0                  |
| Hypoacusis                                       |                    |                     |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      |
| occurrences (all)                                | 0                  | 0                   | 0                  |
| Vertigo                                          |                    |                     |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)      | 0 / 10 (0.00%)      | 0 / 3 (0.00%)      |
| occurrences (all)                                | 0                  | 0                   | 0                  |
| Eye disorders                                    |                    |                     |                    |

|                             |                |                 |                |
|-----------------------------|----------------|-----------------|----------------|
| Dry eye                     |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Iridocyclitis               |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Eyelid irritation           |                |                 |                |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 1              | 0               | 0              |
| Vision blurred              |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Swelling of eyelid          |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Gastrointestinal disorders  |                |                 |                |
| Abdominal discomfort        |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Abdominal distension        |                |                 |                |
| subjects affected / exposed | 2 / 9 (22.22%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 2              | 0               | 0              |
| Abdominal pain              |                |                 |                |
| subjects affected / exposed | 2 / 9 (22.22%) | 2 / 10 (20.00%) | 1 / 3 (33.33%) |
| occurrences (all)           | 2              | 2               | 1              |
| Abdominal pain lower        |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Abdominal pain upper        |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0              |
| Ascites                     |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0              |
| Colitis                     |                |                 |                |

|                                    |                |                 |                |
|------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed        | 1 / 9 (11.11%) | 1 / 10 (10.00%) | 1 / 3 (33.33%) |
| occurrences (all)                  | 3              | 2               | 2              |
| Constipation                       |                |                 |                |
| subjects affected / exposed        | 1 / 9 (11.11%) | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)                  | 1              | 1               | 0              |
| Diarrhoea                          |                |                 |                |
| subjects affected / exposed        | 1 / 9 (11.11%) | 4 / 10 (40.00%) | 1 / 3 (33.33%) |
| occurrences (all)                  | 1              | 7               | 2              |
| Dyspepsia                          |                |                 |                |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Dry mouth                          |                |                 |                |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Dysphagia                          |                |                 |                |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Enteritis                          |                |                 |                |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Flatulence                         |                |                 |                |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Frequent bowel movements           |                |                 |                |
| subjects affected / exposed        | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                  | 1              | 0               | 0              |
| Gastritis                          |                |                 |                |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 2 / 10 (20.00%) | 0 / 3 (0.00%)  |
| occurrences (all)                  | 0              | 3               | 0              |
| Gastrointestinal motility disorder |                |                 |                |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Gastrointestinal haemorrhage       |                |                 |                |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Gastrooesophageal reflux disease   |                |                 |                |

|                                 |                |                 |                |
|---------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)               | 0              | 0               | 0              |
| Immune-mediated enterocolitis   |                |                 |                |
| subjects affected / exposed     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)               | 0              | 0               | 0              |
| Impaired gastric emptying       |                |                 |                |
| subjects affected / exposed     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)               | 0              | 0               | 0              |
| Mouth ulceration                |                |                 |                |
| subjects affected / exposed     | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)               | 1              | 0               | 0              |
| Nausea                          |                |                 |                |
| subjects affected / exposed     | 1 / 9 (11.11%) | 3 / 10 (30.00%) | 0 / 3 (0.00%)  |
| occurrences (all)               | 1              | 3               | 0              |
| Oesophageal varices haemorrhage |                |                 |                |
| subjects affected / exposed     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)               | 0              | 0               | 0              |
| Oral dysaesthesia               |                |                 |                |
| subjects affected / exposed     | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)               | 0              | 1               | 0              |
| Proctalgia                      |                |                 |                |
| subjects affected / exposed     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)               | 0              | 0               | 0              |
| Rectal haemorrhage              |                |                 |                |
| subjects affected / exposed     | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)               | 0              | 1               | 0              |
| Stomatitis                      |                |                 |                |
| subjects affected / exposed     | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 1 / 3 (33.33%) |
| occurrences (all)               | 0              | 1               | 1              |
| Vomiting                        |                |                 |                |
| subjects affected / exposed     | 0 / 9 (0.00%)  | 2 / 10 (20.00%) | 0 / 3 (0.00%)  |
| occurrences (all)               | 0              | 2               | 0              |
| Hepatobiliary disorders         |                |                 |                |
| Biliary obstruction             |                |                 |                |
| subjects affected / exposed     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)               | 0              | 0               | 0              |

|                                        |                |                 |                |
|----------------------------------------|----------------|-----------------|----------------|
| Autoimmune hepatitis                   |                |                 |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 1 / 3 (33.33%) |
| occurrences (all)                      | 0              | 0               | 1              |
| Hepatitis                              |                |                 |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0              |
| Hepatic failure                        |                |                 |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0              |
| Hyperbilirubinaemia                    |                |                 |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)                      | 0              | 1               | 0              |
| Hypertransaminaemia                    |                |                 |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0              |
| Immune-mediated hepatitis              |                |                 |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0              |
| Jaundice cholestatic                   |                |                 |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0              |
| Portal hypertension                    |                |                 |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0              |
| Skin and subcutaneous tissue disorders |                |                 |                |
| Alopecia                               |                |                 |                |
| subjects affected / exposed            | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                      | 1              | 0               | 0              |
| Acquired porokeratosis                 |                |                 |                |
| subjects affected / exposed            | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0              |
| Dermatitis acneiform                   |                |                 |                |
| subjects affected / exposed            | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                      | 1              | 0               | 0              |
| Drug eruption                          |                |                 |                |

|                                             |                |                 |                |
|---------------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed                 | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                           | 0              | 0               | 0              |
| Dry skin                                    |                |                 |                |
| subjects affected / exposed                 | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                           | 1              | 0               | 0              |
| Eczema                                      |                |                 |                |
| subjects affected / exposed                 | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                           | 0              | 0               | 0              |
| Erythema                                    |                |                 |                |
| subjects affected / exposed                 | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                           | 0              | 0               | 0              |
| Ecchymosis                                  |                |                 |                |
| subjects affected / exposed                 | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                           | 0              | 0               | 0              |
| Night sweats                                |                |                 |                |
| subjects affected / exposed                 | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                           | 0              | 0               | 0              |
| Keloid scar                                 |                |                 |                |
| subjects affected / exposed                 | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                           | 0              | 0               | 0              |
| Leukoplakia                                 |                |                 |                |
| subjects affected / exposed                 | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                           | 0              | 0               | 0              |
| Rash                                        |                |                 |                |
| subjects affected / exposed                 | 2 / 9 (22.22%) | 1 / 10 (10.00%) | 1 / 3 (33.33%) |
| occurrences (all)                           | 2              | 1               | 1              |
| Pruritus                                    |                |                 |                |
| subjects affected / exposed                 | 2 / 9 (22.22%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                           | 2              | 0               | 0              |
| Palmar-plantar erythrodysaesthesia syndrome |                |                 |                |
| subjects affected / exposed                 | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                           | 1              | 0               | 0              |
| Rash maculo-papular                         |                |                 |                |
| subjects affected / exposed                 | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)                           | 0              | 1               | 0              |

|                                   |               |                 |                |
|-----------------------------------|---------------|-----------------|----------------|
| Rash macular                      |               |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Rash erythematous                 |               |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Rash pruritic                     |               |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Rash vesicular                    |               |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Transient acantholytic dermatosis |               |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Skin hypopigmentation             |               |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Urticaria                         |               |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Vitiligo                          |               |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Renal and urinary disorders       |               |                 |                |
| Acute kidney injury               |               |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%) | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)                 | 0             | 1               | 0              |
| Pollakiuria                       |               |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Proteinuria                       |               |                 |                |
| subjects affected / exposed       | 0 / 9 (0.00%) | 0 / 10 (0.00%)  | 1 / 3 (33.33%) |
| occurrences (all)                 | 0             | 0               | 1              |
| Haematuria                        |               |                 |                |

|                                                 |                |                 |                |
|-------------------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                               | 1              | 0               | 0              |
| Tubulointerstitial nephritis                    |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 1 / 3 (33.33%) |
| occurrences (all)                               | 0              | 0               | 1              |
| Endocrine disorders                             |                |                 |                |
| Adrenal insufficiency                           |                |                 |                |
| subjects affected / exposed                     | 2 / 9 (22.22%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                               | 2              | 0               | 0              |
| Autoimmune thyroiditis                          |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Hyperthyroidism                                 |                |                 |                |
| subjects affected / exposed                     | 2 / 9 (22.22%) | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)                               | 2              | 1               | 0              |
| Hypophysitis                                    |                |                 |                |
| subjects affected / exposed                     | 2 / 9 (22.22%) | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)                               | 2              | 1               | 0              |
| Hypopituitarism                                 |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Hypothyroidism                                  |                |                 |                |
| subjects affected / exposed                     | 2 / 9 (22.22%) | 1 / 10 (10.00%) | 1 / 3 (33.33%) |
| occurrences (all)                               | 2              | 1               | 1              |
| Thyroiditis                                     |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Inappropriate antidiuretic hormone secretion    |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Musculoskeletal and connective tissue disorders |                |                 |                |
| Arthralgia                                      |                |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Back pain                                       |                |                 |                |

|                             |                |                 |               |
|-----------------------------|----------------|-----------------|---------------|
| subjects affected / exposed | 1 / 9 (11.11%) | 2 / 10 (20.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 1              | 2               | 0             |
| Groin pain                  |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 1               | 0             |
| Hypercreatinaemia           |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Joint swelling              |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Muscular weakness           |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Muscle spasms               |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Musculoskeletal chest pain  |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Myalgia                     |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Myositis                    |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Neck pain                   |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Pain in extremity           |                |                 |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0               | 0             |
| Sacral pain                 |                |                 |               |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)           | 1              | 0               | 0             |
| Infections and infestations |                |                 |               |

|                             |                |                 |                |
|-----------------------------|----------------|-----------------|----------------|
| Bronchitis                  |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Campylobacter infection     |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| COVID-19                    |                |                 |                |
| subjects affected / exposed | 1 / 9 (11.11%) | 2 / 10 (20.00%) | 0 / 3 (0.00%)  |
| occurrences (all)           | 1              | 3               | 0              |
| Candida infection           |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Cellulitis                  |                |                 |                |
| subjects affected / exposed | 2 / 9 (22.22%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 2              | 0               | 0              |
| Conjunctivitis              |                |                 |                |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 1              | 0               | 0              |
| Cystitis                    |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Diverticulitis              |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 1 / 3 (33.33%) |
| occurrences (all)           | 0              | 0               | 1              |
| Eye infection bacterial     |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Folliculitis                |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Gastroenteritis             |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Hepatitis viral             |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |

|                             |                |                |               |
|-----------------------------|----------------|----------------|---------------|
| Gastrointestinal infection  |                |                |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Herpes zoster               |                |                |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Hordeolum                   |                |                |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Influenza                   |                |                |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Localised infection         |                |                |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Mucosal infection           |                |                |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Nasopharyngitis             |                |                |               |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 1              | 0              | 0             |
| Oral candidiasis            |                |                |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Norovirus infection         |                |                |               |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 1              | 0              | 0             |
| Pharyngitis                 |                |                |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Rash pustular               |                |                |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Pneumonia                   |                |                |               |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |

|                                    |                |                 |               |
|------------------------------------|----------------|-----------------|---------------|
| Soft tissue infection              |                |                 |               |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                  | 0              | 0               | 0             |
| Skin infection                     |                |                 |               |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                  | 0              | 0               | 0             |
| Spontaneous bacterial peritonitis  |                |                 |               |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                  | 0              | 0               | 0             |
| Upper respiratory tract infection  |                |                 |               |
| subjects affected / exposed        | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                  | 1              | 0               | 0             |
| Urinary tract infection            |                |                 |               |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                  | 0              | 0               | 0             |
| Staphylococcal infection           |                |                 |               |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                  | 0              | 0               | 0             |
| Vascular access site infection     |                |                 |               |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                  | 0              | 0               | 0             |
| Viral infection                    |                |                 |               |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%) |
| occurrences (all)                  | 0              | 0               | 0             |
| Metabolism and nutrition disorders |                |                 |               |
| Decreased appetite                 |                |                 |               |
| subjects affected / exposed        | 1 / 9 (11.11%) | 3 / 10 (30.00%) | 0 / 3 (0.00%) |
| occurrences (all)                  | 2              | 3               | 0             |
| Dehydration                        |                |                 |               |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)                  | 0              | 1               | 0             |
| Electrolyte imbalance              |                |                 |               |
| subjects affected / exposed        | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%) |
| occurrences (all)                  | 0              | 1               | 0             |
| Hyperglycaemia                     |                |                 |               |

|                             |                |                 |                |
|-----------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Hypercalcaemia              |                |                 |                |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 1              | 0               | 0              |
| Hyperkalaemia               |                |                 |                |
| subjects affected / exposed | 1 / 9 (11.11%) | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)           | 1              | 1               | 0              |
| Hypermagnesaemia            |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Hyperlipasaemia             |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Hyperuricaemia              |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Hypernatraemia              |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Hypoalbuminaemia            |                |                 |                |
| subjects affected / exposed | 1 / 9 (11.11%) | 2 / 10 (20.00%) | 0 / 3 (0.00%)  |
| occurrences (all)           | 1              | 2               | 0              |
| Hypocalcaemia               |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0              |
| Hypochloraemia              |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Hypokalaemia                |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 2 / 10 (20.00%) | 1 / 3 (33.33%) |
| occurrences (all)           | 0              | 2               | 1              |
| Hypomagnesaemia             |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 3 / 10 (30.00%) | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 3               | 0              |
| Hyponatraemia               |                |                 |                |

|                             |                |                 |                |
|-----------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 2 / 9 (22.22%) | 1 / 10 (10.00%) | 1 / 3 (33.33%) |
| occurrences (all)           | 3              | 1               | 1              |
| Hypovolaemia                |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Hypophosphataemia           |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Iron deficiency             |                |                 |                |
| subjects affected / exposed | 0 / 9 (0.00%)  | 1 / 10 (10.00%) | 0 / 3 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0              |
| Malnutrition                |                |                 |                |
| subjects affected / exposed | 1 / 9 (11.11%) | 0 / 10 (0.00%)  | 0 / 3 (0.00%)  |
| occurrences (all)           | 1              | 0               | 0              |

| <b>Non-serious adverse events</b>                                   | Part 2A: Melanoma<br>Arms BMS-986249<br>800mg IV Q3W | Part 2A: Melanoma<br>Arms BMS-986249<br>1200mg IV Q3W | Part 2A: Melanoma<br>Arms Ipilimumab<br>3mg/kg IV Q3W |
|---------------------------------------------------------------------|------------------------------------------------------|-------------------------------------------------------|-------------------------------------------------------|
| Total subjects affected by non-serious adverse events               |                                                      |                                                       |                                                       |
| subjects affected / exposed                                         | 3 / 3 (100.00%)                                      | 57 / 57 (100.00%)                                     | 57 / 58 (98.28%)                                      |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                                      |                                                       |                                                       |
| Acrochordon                                                         |                                                      |                                                       |                                                       |
| subjects affected / exposed                                         | 0 / 3 (0.00%)                                        | 0 / 57 (0.00%)                                        | 0 / 58 (0.00%)                                        |
| occurrences (all)                                                   | 0                                                    | 0                                                     | 0                                                     |
| Malignant neoplasm progression                                      |                                                      |                                                       |                                                       |
| subjects affected / exposed                                         | 0 / 3 (0.00%)                                        | 0 / 57 (0.00%)                                        | 1 / 58 (1.72%)                                        |
| occurrences (all)                                                   | 0                                                    | 0                                                     | 1                                                     |
| Cancer pain                                                         |                                                      |                                                       |                                                       |
| subjects affected / exposed                                         | 0 / 3 (0.00%)                                        | 3 / 57 (5.26%)                                        | 5 / 58 (8.62%)                                        |
| occurrences (all)                                                   | 0                                                    | 3                                                     | 5                                                     |
| Tumour pain                                                         |                                                      |                                                       |                                                       |
| subjects affected / exposed                                         | 0 / 3 (0.00%)                                        | 0 / 57 (0.00%)                                        | 1 / 58 (1.72%)                                        |
| occurrences (all)                                                   | 0                                                    | 0                                                     | 1                                                     |
| Metastases to central nervous system                                |                                                      |                                                       |                                                       |
| subjects affected / exposed                                         | 0 / 3 (0.00%)                                        | 0 / 57 (0.00%)                                        | 0 / 58 (0.00%)                                        |
| occurrences (all)                                                   | 0                                                    | 0                                                     | 0                                                     |
| Vascular disorders                                                  |                                                      |                                                       |                                                       |

|                                                      |               |                  |                 |
|------------------------------------------------------|---------------|------------------|-----------------|
| Deep vein thrombosis                                 |               |                  |                 |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 2 / 57 (3.51%)   | 2 / 58 (3.45%)  |
| occurrences (all)                                    | 0             | 2                | 2               |
| Haematoma                                            |               |                  |                 |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)  |
| occurrences (all)                                    | 0             | 0                | 0               |
| Haemorrhage                                          |               |                  |                 |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)  |
| occurrences (all)                                    | 0             | 0                | 0               |
| Hot flush                                            |               |                  |                 |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 1 / 58 (1.72%)  |
| occurrences (all)                                    | 0             | 0                | 1               |
| Hypertension                                         |               |                  |                 |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 3 / 57 (5.26%)   | 7 / 58 (12.07%) |
| occurrences (all)                                    | 0             | 4                | 11              |
| Hypotension                                          |               |                  |                 |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 4 / 57 (7.02%)   | 3 / 58 (5.17%)  |
| occurrences (all)                                    | 0             | 5                | 4               |
| Pallor                                               |               |                  |                 |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)  |
| occurrences (all)                                    | 0             | 0                | 0               |
| Venous thrombosis                                    |               |                  |                 |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)  |
| occurrences (all)                                    | 0             | 0                | 0               |
| General disorders and administration site conditions |               |                  |                 |
| Asthenia                                             |               |                  |                 |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 13 / 57 (22.81%) | 5 / 58 (8.62%)  |
| occurrences (all)                                    | 0             | 15               | 6               |
| Application site reaction                            |               |                  |                 |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)  |
| occurrences (all)                                    | 0             | 0                | 0               |
| Axillary pain                                        |               |                  |                 |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 3 / 57 (5.26%)   | 0 / 58 (0.00%)  |
| occurrences (all)                                    | 0             | 3                | 0               |
| Chest discomfort                                     |               |                  |                 |

|                                     |                 |                  |                  |
|-------------------------------------|-----------------|------------------|------------------|
| subjects affected / exposed         | 0 / 3 (0.00%)   | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                   | 0               | 0                | 0                |
| Chest pain                          |                 |                  |                  |
| subjects affected / exposed         | 0 / 3 (0.00%)   | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)                   | 0               | 0                | 1                |
| Chills                              |                 |                  |                  |
| subjects affected / exposed         | 0 / 3 (0.00%)   | 2 / 57 (3.51%)   | 0 / 58 (0.00%)   |
| occurrences (all)                   | 0               | 2                | 0                |
| Complication associated with device |                 |                  |                  |
| subjects affected / exposed         | 0 / 3 (0.00%)   | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                   | 0               | 0                | 0                |
| Device related thrombosis           |                 |                  |                  |
| subjects affected / exposed         | 0 / 3 (0.00%)   | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                   | 0               | 0                | 0                |
| Gait disturbance                    |                 |                  |                  |
| subjects affected / exposed         | 0 / 3 (0.00%)   | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                   | 0               | 0                | 0                |
| Fatigue                             |                 |                  |                  |
| subjects affected / exposed         | 3 / 3 (100.00%) | 15 / 57 (26.32%) | 19 / 58 (32.76%) |
| occurrences (all)                   | 3               | 18               | 26               |
| Hernia pain                         |                 |                  |                  |
| subjects affected / exposed         | 0 / 3 (0.00%)   | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                   | 0               | 0                | 0                |
| Injection site extravasation        |                 |                  |                  |
| subjects affected / exposed         | 0 / 3 (0.00%)   | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                   | 0               | 0                | 0                |
| Influenza like illness              |                 |                  |                  |
| subjects affected / exposed         | 0 / 3 (0.00%)   | 3 / 57 (5.26%)   | 1 / 58 (1.72%)   |
| occurrences (all)                   | 0               | 4                | 1                |
| Localised oedema                    |                 |                  |                  |
| subjects affected / exposed         | 0 / 3 (0.00%)   | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                   | 0               | 0                | 0                |
| Mucosal inflammation                |                 |                  |                  |
| subjects affected / exposed         | 0 / 3 (0.00%)   | 2 / 57 (3.51%)   | 5 / 58 (8.62%)   |
| occurrences (all)                   | 0               | 2                | 6                |
| Malaise                             |                 |                  |                  |

|                                          |                |                  |                  |
|------------------------------------------|----------------|------------------|------------------|
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                        | 0              | 0                | 0                |
| Non-cardiac chest pain                   |                |                  |                  |
| subjects affected / exposed              | 1 / 3 (33.33%) | 1 / 57 (1.75%)   | 0 / 58 (0.00%)   |
| occurrences (all)                        | 1              | 1                | 0                |
| Oedema peripheral                        |                |                  |                  |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 7 / 57 (12.28%)  | 7 / 58 (12.07%)  |
| occurrences (all)                        | 0              | 8                | 8                |
| Pain                                     |                |                  |                  |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                        | 0              | 0                | 0                |
| Performance status decreased             |                |                  |                  |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                        | 0              | 0                | 0                |
| Peripheral swelling                      |                |                  |                  |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                        | 0              | 0                | 0                |
| Pyrexia                                  |                |                  |                  |
| subjects affected / exposed              | 1 / 3 (33.33%) | 14 / 57 (24.56%) | 11 / 58 (18.97%) |
| occurrences (all)                        | 2              | 23               | 23               |
| Swelling face                            |                |                  |                  |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)                        | 0              | 0                | 1                |
| Xerosis                                  |                |                  |                  |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 4 / 57 (7.02%)   | 8 / 58 (13.79%)  |
| occurrences (all)                        | 0              | 4                | 8                |
| Temperature intolerance                  |                |                  |                  |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                        | 0              | 0                | 0                |
| Immune system disorders                  |                |                  |                  |
| Seasonal allergy                         |                |                  |                  |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                        | 0              | 0                | 0                |
| Reproductive system and breast disorders |                |                  |                  |

|                                                                              |                     |                      |                      |
|------------------------------------------------------------------------------|---------------------|----------------------|----------------------|
| Heavy menstrual bleeding<br>subjects affected / exposed<br>occurrences (all) | 0 / 3 (0.00%)<br>0  | 0 / 57 (0.00%)<br>0  | 0 / 58 (0.00%)<br>0  |
| Breast pain<br>subjects affected / exposed<br>occurrences (all)              | 0 / 3 (0.00%)<br>0  | 0 / 57 (0.00%)<br>0  | 0 / 58 (0.00%)<br>0  |
| Vulvovaginal pruritus<br>subjects affected / exposed<br>occurrences (all)    | 0 / 3 (0.00%)<br>0  | 0 / 57 (0.00%)<br>0  | 0 / 58 (0.00%)<br>0  |
| Respiratory, thoracic and mediastinal disorders                              |                     |                      |                      |
| Apnoea<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 3 (0.00%)<br>0  | 0 / 57 (0.00%)<br>0  | 0 / 58 (0.00%)<br>0  |
| Cough<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 3 (0.00%)<br>0  | 8 / 57 (14.04%)<br>9 | 7 / 58 (12.07%)<br>8 |
| Dysphonia<br>subjects affected / exposed<br>occurrences (all)                | 0 / 3 (0.00%)<br>0  | 0 / 57 (0.00%)<br>0  | 0 / 58 (0.00%)<br>0  |
| Dyspnoea<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 3 (33.33%)<br>1 | 6 / 57 (10.53%)<br>6 | 4 / 58 (6.90%)<br>5  |
| Nasal congestion<br>subjects affected / exposed<br>occurrences (all)         | 0 / 3 (0.00%)<br>0  | 0 / 57 (0.00%)<br>0  | 2 / 58 (3.45%)<br>5  |
| Hypoxia<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 3 (0.00%)<br>0  | 0 / 57 (0.00%)<br>0  | 0 / 58 (0.00%)<br>0  |
| Haemoptysis<br>subjects affected / exposed<br>occurrences (all)              | 0 / 3 (0.00%)<br>0  | 0 / 57 (0.00%)<br>0  | 0 / 58 (0.00%)<br>0  |
| Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)       | 0 / 3 (0.00%)<br>0  | 0 / 57 (0.00%)<br>0  | 2 / 58 (3.45%)<br>5  |
| Pleural effusion                                                             |                     |                      |                      |

|                                         |               |                |                |
|-----------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)                       | 0             | 0              | 0              |
| Pneumonitis                             |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 3 / 57 (5.26%) | 2 / 58 (3.45%) |
| occurrences (all)                       | 0             | 3              | 2              |
| Pneumothorax                            |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)                       | 0             | 0              | 0              |
| Pulmonary embolism                      |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 5 / 57 (8.77%) | 3 / 58 (5.17%) |
| occurrences (all)                       | 0             | 5              | 3              |
| Rhinitis allergic                       |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences (all)                       | 0             | 1              | 0              |
| Rhinorrhoea                             |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences (all)                       | 0             | 1              | 0              |
| Upper-airway cough syndrome             |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)                       | 0             | 0              | 0              |
| Wheezing                                |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)                       | 0             | 0              | 0              |
| Psychiatric disorders                   |               |                |                |
| Adjustment disorder with depressed mood |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)                       | 0             | 0              | 0              |
| Affective disorder                      |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 1 / 58 (1.72%) |
| occurrences (all)                       | 0             | 1              | 1              |
| Anxiety                                 |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 2 / 58 (3.45%) |
| occurrences (all)                       | 0             | 0              | 2              |
| Depression                              |               |                |                |

|                                      |                |                  |                  |
|--------------------------------------|----------------|------------------|------------------|
| subjects affected / exposed          | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 2 / 58 (3.45%)   |
| occurrences (all)                    | 0              | 1                | 2                |
| Disorientation                       |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                    | 0              | 0                | 0                |
| Insomnia                             |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 3 / 57 (5.26%)   | 5 / 58 (8.62%)   |
| occurrences (all)                    | 0              | 3                | 5                |
| Libido decreased                     |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 0 / 58 (0.00%)   |
| occurrences (all)                    | 0              | 1                | 0                |
| Mental status changes                |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                    | 0              | 0                | 0                |
| Panic attack                         |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                    | 0              | 0                | 0                |
| Investigations                       |                |                  |                  |
| Ammonia increased                    |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                    | 0              | 0                | 0                |
| Alanine aminotransferase increased   |                |                  |                  |
| subjects affected / exposed          | 2 / 3 (66.67%) | 25 / 57 (43.86%) | 22 / 58 (37.93%) |
| occurrences (all)                    | 3              | 36               | 34               |
| Amylase increased                    |                |                  |                  |
| subjects affected / exposed          | 2 / 3 (66.67%) | 9 / 57 (15.79%)  | 7 / 58 (12.07%)  |
| occurrences (all)                    | 2              | 14               | 11               |
| Blood albumin decreased              |                |                  |                  |
| subjects affected / exposed          | 1 / 3 (33.33%) | 4 / 57 (7.02%)   | 6 / 58 (10.34%)  |
| occurrences (all)                    | 1              | 5                | 7                |
| Aspartate aminotransferase increased |                |                  |                  |
| subjects affected / exposed          | 2 / 3 (66.67%) | 21 / 57 (36.84%) | 25 / 58 (43.10%) |
| occurrences (all)                    | 4              | 35               | 40               |
| Blood bilirubin increased            |                |                  |                  |

|                                        |                |                  |                  |
|----------------------------------------|----------------|------------------|------------------|
| subjects affected / exposed            | 1 / 3 (33.33%) | 3 / 57 (5.26%)   | 6 / 58 (10.34%)  |
| occurrences (all)                      | 2              | 5                | 8                |
| Blood alkaline phosphatase increased   |                |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 4 / 57 (7.02%)   | 7 / 58 (12.07%)  |
| occurrences (all)                      | 0              | 5                | 10               |
| Blood calcium decreased                |                |                  |                  |
| subjects affected / exposed            | 1 / 3 (33.33%) | 5 / 57 (8.77%)   | 3 / 58 (5.17%)   |
| occurrences (all)                      | 1              | 8                | 3                |
| Blood calcium increased                |                |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 2 / 58 (3.45%)   |
| occurrences (all)                      | 0              | 1                | 2                |
| Blood cholesterol increased            |                |                  |                  |
| subjects affected / exposed            | 1 / 3 (33.33%) | 5 / 57 (8.77%)   | 5 / 58 (8.62%)   |
| occurrences (all)                      | 1              | 10               | 11               |
| Blood creatine phosphokinase increased |                |                  |                  |
| subjects affected / exposed            | 1 / 3 (33.33%) | 10 / 57 (17.54%) | 10 / 58 (17.24%) |
| occurrences (all)                      | 2              | 14               | 17               |
| Blood creatinine increased             |                |                  |                  |
| subjects affected / exposed            | 1 / 3 (33.33%) | 12 / 57 (21.05%) | 10 / 58 (17.24%) |
| occurrences (all)                      | 1              | 16               | 19               |
| Blood glucose decreased                |                |                  |                  |
| subjects affected / exposed            | 1 / 3 (33.33%) | 1 / 57 (1.75%)   | 0 / 58 (0.00%)   |
| occurrences (all)                      | 1              | 1                | 0                |
| Blood lactic acid increased            |                |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                      | 0              | 0                | 0                |
| Blood glucose increased                |                |                  |                  |
| subjects affected / exposed            | 2 / 3 (66.67%) | 10 / 57 (17.54%) | 10 / 58 (17.24%) |
| occurrences (all)                      | 3              | 15               | 14               |
| Blood magnesium decreased              |                |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 4 / 57 (7.02%)   | 9 / 58 (15.52%)  |
| occurrences (all)                      | 0              | 9                | 13               |
| Blood phosphorus increased             |                |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)                      | 0              | 0                | 1                |

|                                             |                |                 |                 |
|---------------------------------------------|----------------|-----------------|-----------------|
| Blood potassium decreased                   |                |                 |                 |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 3 / 57 (5.26%)  | 1 / 58 (1.72%)  |
| occurrences (all)                           | 0              | 3               | 1               |
| Blood prolactin increased                   |                |                 |                 |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 57 (0.00%)  | 0 / 58 (0.00%)  |
| occurrences (all)                           | 0              | 0               | 0               |
| Blood sodium decreased                      |                |                 |                 |
| subjects affected / exposed                 | 1 / 3 (33.33%) | 6 / 57 (10.53%) | 8 / 58 (13.79%) |
| occurrences (all)                           | 1              | 8               | 10              |
| Blood thyroid stimulating hormone decreased |                |                 |                 |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 2 / 57 (3.51%)  | 1 / 58 (1.72%)  |
| occurrences (all)                           | 0              | 2               | 1               |
| Blood thyroid stimulating hormone increased |                |                 |                 |
| subjects affected / exposed                 | 1 / 3 (33.33%) | 9 / 57 (15.79%) | 8 / 58 (13.79%) |
| occurrences (all)                           | 1              | 10              | 10              |
| Blood uric acid increased                   |                |                 |                 |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 1 / 57 (1.75%)  | 0 / 58 (0.00%)  |
| occurrences (all)                           | 0              | 1               | 0               |
| C-reactive protein increased                |                |                 |                 |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 1 / 57 (1.75%)  | 1 / 58 (1.72%)  |
| occurrences (all)                           | 0              | 1               | 1               |
| Cardiac murmur                              |                |                 |                 |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 57 (0.00%)  | 0 / 58 (0.00%)  |
| occurrences (all)                           | 0              | 0               | 0               |
| Gamma-glutamyltransferase increased         |                |                 |                 |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 7 / 57 (12.28%) | 4 / 58 (6.90%)  |
| occurrences (all)                           | 0              | 7               | 5               |
| Haemoglobin decreased                       |                |                 |                 |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 57 (0.00%)  | 2 / 58 (3.45%)  |
| occurrences (all)                           | 0              | 0               | 3               |
| International normalised ratio increased    |                |                 |                 |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 57 (0.00%)  | 0 / 58 (0.00%)  |
| occurrences (all)                           | 0              | 0               | 0               |
| Lipase increased                            |                |                 |                 |

|                                  |                |                  |                  |
|----------------------------------|----------------|------------------|------------------|
| subjects affected / exposed      | 2 / 3 (66.67%) | 11 / 57 (19.30%) | 13 / 58 (22.41%) |
| occurrences (all)                | 5              | 16               | 19               |
| Liver function test increased    |                |                  |                  |
| subjects affected / exposed      | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                | 0              | 0                | 0                |
| Neutrophil count decreased       |                |                  |                  |
| subjects affected / exposed      | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 1 / 58 (1.72%)   |
| occurrences (all)                | 0              | 2                | 1                |
| Platelet count decreased         |                |                  |                  |
| subjects affected / exposed      | 1 / 3 (33.33%) | 1 / 57 (1.75%)   | 1 / 58 (1.72%)   |
| occurrences (all)                | 2              | 1                | 1                |
| Troponin I increased             |                |                  |                  |
| subjects affected / exposed      | 0 / 3 (0.00%)  | 3 / 57 (5.26%)   | 1 / 58 (1.72%)   |
| occurrences (all)                | 0              | 3                | 1                |
| Transaminases increased          |                |                  |                  |
| subjects affected / exposed      | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 4 / 58 (6.90%)   |
| occurrences (all)                | 0              | 2                | 4                |
| Troponin increased               |                |                  |                  |
| subjects affected / exposed      | 0 / 3 (0.00%)  | 6 / 57 (10.53%)  | 5 / 58 (8.62%)   |
| occurrences (all)                | 0              | 6                | 6                |
| Urine phosphorus increased       |                |                  |                  |
| subjects affected / exposed      | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                | 0              | 0                | 0                |
| Urine calcium increased          |                |                  |                  |
| subjects affected / exposed      | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                | 0              | 0                | 0                |
| Weight decreased                 |                |                  |                  |
| subjects affected / exposed      | 0 / 3 (0.00%)  | 2 / 57 (3.51%)   | 5 / 58 (8.62%)   |
| occurrences (all)                | 0              | 2                | 5                |
| White blood cell count decreased |                |                  |                  |
| subjects affected / exposed      | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 0 / 58 (0.00%)   |
| occurrences (all)                | 0              | 1                | 0                |
| White blood cell count increased |                |                  |                  |
| subjects affected / exposed      | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                | 0              | 0                | 0                |
| Injury, poisoning and procedural |                |                  |                  |

|                               |               |                |                |
|-------------------------------|---------------|----------------|----------------|
| complications                 |               |                |                |
| Fall                          |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences (all)             | 0             | 0              | 1              |
| Femur fracture                |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Infusion related reaction     |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Muscle strain                 |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Lip injury                    |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Procedural pain               |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Rib fracture                  |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Skin abrasion                 |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Tooth fracture                |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Vascular access site erythema |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Wound secretion               |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Cardiac disorders             |               |                |                |

|                             |               |                  |                  |
|-----------------------------|---------------|------------------|------------------|
| Atrial fibrillation         |               |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 57 (1.75%)   | 1 / 58 (1.72%)   |
| occurrences (all)           | 0             | 1                | 1                |
| Palpitations                |               |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0             | 0                | 0                |
| Pericardial effusion        |               |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 57 (1.75%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0             | 1                | 0                |
| Sinus bradycardia           |               |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0             | 0                | 0                |
| Sinus tachycardia           |               |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0             | 0                | 0                |
| Tachycardia                 |               |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 57 (1.75%)   | 1 / 58 (1.72%)   |
| occurrences (all)           | 0             | 1                | 1                |
| Nervous system disorders    |               |                  |                  |
| Aphasia                     |               |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0             | 0                | 0                |
| Cognitive disorder          |               |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0             | 0                | 0                |
| Dysarthria                  |               |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 57 (1.75%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0             | 1                | 0                |
| Dizziness                   |               |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%) | 5 / 57 (8.77%)   | 2 / 58 (3.45%)   |
| occurrences (all)           | 0             | 5                | 2                |
| Headache                    |               |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%) | 10 / 57 (17.54%) | 10 / 58 (17.24%) |
| occurrences (all)           | 0             | 11               | 15               |
| Dysgeusia                   |               |                  |                  |

|                               |               |                |                |
|-------------------------------|---------------|----------------|----------------|
| subjects affected / exposed   | 0 / 3 (0.00%) | 2 / 57 (3.51%) | 1 / 58 (1.72%) |
| occurrences (all)             | 0             | 2              | 1              |
| Hyperaesthesia                |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Lethargy                      |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Neuralgia                     |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 1              | 0              |
| Neuropathy peripheral         |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences (all)             | 0             | 0              | 1              |
| Paraesthesia                  |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 2 / 57 (3.51%) | 2 / 58 (3.45%) |
| occurrences (all)             | 0             | 2              | 2              |
| Parkinson's disease           |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Peripheral sensory neuropathy |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Peripheral motor neuropathy   |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Post herpetic neuralgia       |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Restless legs syndrome        |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Radiculopathy                 |               |                |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)             | 0             | 0              | 0              |
| Somnolence                    |               |                |                |

|                                      |                |                  |                  |
|--------------------------------------|----------------|------------------|------------------|
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                    | 0              | 0                | 0                |
| Sciatica                             |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)                    | 0              | 0                | 2                |
| Tension headache                     |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                    | 0              | 0                | 0                |
| Tremor                               |                |                  |                  |
| subjects affected / exposed          | 1 / 3 (33.33%) | 2 / 57 (3.51%)   | 1 / 58 (1.72%)   |
| occurrences (all)                    | 1              | 2                | 1                |
| Blood and lymphatic system disorders |                |                  |                  |
| Anaemia                              |                |                  |                  |
| subjects affected / exposed          | 2 / 3 (66.67%) | 27 / 57 (47.37%) | 31 / 58 (53.45%) |
| occurrences (all)                    | 3              | 33               | 48               |
| Eosinophilia                         |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 1 / 58 (1.72%)   |
| occurrences (all)                    | 0              | 1                | 1                |
| Iron deficiency anaemia              |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)                    | 0              | 0                | 1                |
| Leukocytosis                         |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)                    | 0              | 0                | 1                |
| Lymphopenia                          |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)                    | 0              | 0                | 1                |
| Thrombocytopenia                     |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 2 / 57 (3.51%)   | 1 / 58 (1.72%)   |
| occurrences (all)                    | 0              | 2                | 1                |
| Neutropenia                          |                |                  |                  |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 2 / 58 (3.45%)   |
| occurrences (all)                    | 0              | 2                | 2                |
| Ear and labyrinth disorders          |                |                  |                  |
| Ear pain                             |                |                  |                  |

|                             |                |                  |                |
|-----------------------------|----------------|------------------|----------------|
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%) |
| occurrences (all)           | 0              | 0                | 0              |
| Hypoacusis                  |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%) |
| occurrences (all)           | 0              | 0                | 1              |
| Vertigo                     |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 3 / 57 (5.26%)   | 2 / 58 (3.45%) |
| occurrences (all)           | 0              | 3                | 2              |
| Eye disorders               |                |                  |                |
| Dry eye                     |                |                  |                |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 57 (0.00%)   | 1 / 58 (1.72%) |
| occurrences (all)           | 1              | 0                | 1              |
| Iridocyclitis               |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%) |
| occurrences (all)           | 0              | 0                | 1              |
| Eyelid irritation           |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%) |
| occurrences (all)           | 0              | 0                | 0              |
| Vision blurred              |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 4 / 58 (6.90%) |
| occurrences (all)           | 0              | 1                | 4              |
| Swelling of eyelid          |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%) |
| occurrences (all)           | 0              | 0                | 0              |
| Gastrointestinal disorders  |                |                  |                |
| Abdominal discomfort        |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%) |
| occurrences (all)           | 0              | 0                | 0              |
| Abdominal distension        |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%) |
| occurrences (all)           | 0              | 0                | 0              |
| Abdominal pain              |                |                  |                |
| subjects affected / exposed | 1 / 3 (33.33%) | 10 / 57 (17.54%) | 3 / 58 (5.17%) |
| occurrences (all)           | 1              | 12               | 4              |
| Abdominal pain lower        |                |                  |                |

|                             |                |                  |                  |
|-----------------------------|----------------|------------------|------------------|
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Abdominal pain upper        |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 2 / 57 (3.51%)   | 2 / 58 (3.45%)   |
| occurrences (all)           | 0              | 2                | 2                |
| Ascites                     |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 1                | 0                |
| Colitis                     |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 5 / 57 (8.77%)   | 1 / 58 (1.72%)   |
| occurrences (all)           | 0              | 7                | 1                |
| Constipation                |                |                  |                  |
| subjects affected / exposed | 1 / 3 (33.33%) | 8 / 57 (14.04%)  | 9 / 58 (15.52%)  |
| occurrences (all)           | 1              | 9                | 12               |
| Diarrhoea                   |                |                  |                  |
| subjects affected / exposed | 2 / 3 (66.67%) | 25 / 57 (43.86%) | 19 / 58 (32.76%) |
| occurrences (all)           | 3              | 38               | 27               |
| Dyspepsia                   |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Dry mouth                   |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 2 / 58 (3.45%)   |
| occurrences (all)           | 0              | 1                | 2                |
| Dysphagia                   |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)           | 0              | 0                | 1                |
| Enteritis                   |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Flatulence                  |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 3 / 58 (5.17%)   |
| occurrences (all)           | 0              | 1                | 3                |
| Frequent bowel movements    |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Gastritis                   |                |                  |                  |

|                                    |                |                  |                  |
|------------------------------------|----------------|------------------|------------------|
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)                  | 0              | 0                | 1                |
| Gastrointestinal motility disorder |                |                  |                  |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                  | 0              | 0                | 0                |
| Gastrointestinal haemorrhage       |                |                  |                  |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                  | 0              | 0                | 0                |
| Gastrooesophageal reflux disease   |                |                  |                  |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)                  | 0              | 0                | 1                |
| Immune-mediated enterocolitis      |                |                  |                  |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 2 / 57 (3.51%)   | 0 / 58 (0.00%)   |
| occurrences (all)                  | 0              | 2                | 0                |
| Impaired gastric emptying          |                |                  |                  |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                  | 0              | 0                | 0                |
| Mouth ulceration                   |                |                  |                  |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                  | 0              | 0                | 0                |
| Nausea                             |                |                  |                  |
| subjects affected / exposed        | 2 / 3 (66.67%) | 18 / 57 (31.58%) | 19 / 58 (32.76%) |
| occurrences (all)                  | 2              | 21               | 29               |
| Oesophageal varices haemorrhage    |                |                  |                  |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                  | 0              | 0                | 0                |
| Oral dysaesthesia                  |                |                  |                  |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                  | 0              | 0                | 0                |
| Proctalgia                         |                |                  |                  |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 2 / 58 (3.45%)   |
| occurrences (all)                  | 0              | 0                | 3                |
| Rectal haemorrhage                 |                |                  |                  |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 1 / 58 (1.72%)   |
| occurrences (all)                  | 0              | 1                | 1                |
| Stomatitis                         |                |                  |                  |

|                                        |               |                  |                  |
|----------------------------------------|---------------|------------------|------------------|
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)                      | 0             | 0                | 1                |
| Vomiting                               |               |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%) | 12 / 57 (21.05%) | 12 / 58 (20.69%) |
| occurrences (all)                      | 0             | 15               | 14               |
| Hepatobiliary disorders                |               |                  |                  |
| Biliary obstruction                    |               |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                      | 0             | 0                | 0                |
| Autoimmune hepatitis                   |               |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                      | 0             | 0                | 0                |
| Hepatitis                              |               |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%) | 4 / 57 (7.02%)   | 2 / 58 (3.45%)   |
| occurrences (all)                      | 0             | 4                | 2                |
| Hepatic failure                        |               |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                      | 0             | 0                | 0                |
| Hyperbilirubinaemia                    |               |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%) | 1 / 57 (1.75%)   | 1 / 58 (1.72%)   |
| occurrences (all)                      | 0             | 1                | 1                |
| Hypertransaminaemia                    |               |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%) | 6 / 57 (10.53%)  | 1 / 58 (1.72%)   |
| occurrences (all)                      | 0             | 6                | 1                |
| Immune-mediated hepatitis              |               |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 4 / 58 (6.90%)   |
| occurrences (all)                      | 0             | 0                | 6                |
| Jaundice cholestatic                   |               |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                      | 0             | 0                | 0                |
| Portal hypertension                    |               |                  |                  |
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                      | 0             | 0                | 0                |
| Skin and subcutaneous tissue disorders |               |                  |                  |
| Alopecia                               |               |                  |                  |

|                             |                |                  |                  |
|-----------------------------|----------------|------------------|------------------|
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)           | 1              | 0                | 1                |
| Acquired porokeratosis      |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Dermatitis acneiform        |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)           | 0              | 0                | 1                |
| Drug eruption               |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Dry skin                    |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 2 / 58 (3.45%)   |
| occurrences (all)           | 0              | 0                | 3                |
| Eczema                      |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Erythema                    |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 4 / 58 (6.90%)   |
| occurrences (all)           | 0              | 1                | 4                |
| Ecchymosis                  |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Night sweats                |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 1 / 58 (1.72%)   |
| occurrences (all)           | 0              | 1                | 1                |
| Keloid scar                 |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Leukoplakia                 |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Rash                        |                |                  |                  |
| subjects affected / exposed | 1 / 3 (33.33%) | 17 / 57 (29.82%) | 18 / 58 (31.03%) |
| occurrences (all)           | 1              | 21               | 21               |
| Pruritus                    |                |                  |                  |

|                                             |                |                  |                  |
|---------------------------------------------|----------------|------------------|------------------|
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 22 / 57 (38.60%) | 25 / 58 (43.10%) |
| occurrences (all)                           | 0              | 28               | 41               |
| Palmar-plantar erythrodysaesthesia syndrome |                |                  |                  |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                           | 0              | 0                | 0                |
| Rash maculo-papular                         |                |                  |                  |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 9 / 57 (15.79%)  | 11 / 58 (18.97%) |
| occurrences (all)                           | 0              | 9                | 13               |
| Rash macular                                |                |                  |                  |
| subjects affected / exposed                 | 1 / 3 (33.33%) | 3 / 57 (5.26%)   | 1 / 58 (1.72%)   |
| occurrences (all)                           | 1              | 3                | 1                |
| Rash erythematous                           |                |                  |                  |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 4 / 57 (7.02%)   | 1 / 58 (1.72%)   |
| occurrences (all)                           | 0              | 4                | 1                |
| Rash pruritic                               |                |                  |                  |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                           | 0              | 0                | 0                |
| Rash vesicular                              |                |                  |                  |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                           | 0              | 0                | 0                |
| Transient acantholytic dermatosis           |                |                  |                  |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                           | 0              | 0                | 0                |
| Skin hypopigmentation                       |                |                  |                  |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 2 / 58 (3.45%)   |
| occurrences (all)                           | 0              | 0                | 2                |
| Urticaria                                   |                |                  |                  |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                           | 0              | 0                | 0                |
| Vitiligo                                    |                |                  |                  |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 7 / 57 (12.28%)  | 7 / 58 (12.07%)  |
| occurrences (all)                           | 0              | 7                | 7                |
| Renal and urinary disorders                 |                |                  |                  |
| Acute kidney injury                         |                |                  |                  |

|                              |                |                  |                  |
|------------------------------|----------------|------------------|------------------|
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)            | 0              | 0                | 1                |
| Pollakiuria                  |                |                  |                  |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 0 / 58 (0.00%)   |
| occurrences (all)            | 0              | 1                | 0                |
| Proteinuria                  |                |                  |                  |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)            | 0              | 0                | 1                |
| Haematuria                   |                |                  |                  |
| subjects affected / exposed  | 1 / 3 (33.33%) | 2 / 57 (3.51%)   | 1 / 58 (1.72%)   |
| occurrences (all)            | 1              | 2                | 1                |
| Tubulointerstitial nephritis |                |                  |                  |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)            | 0              | 0                | 0                |
| Endocrine disorders          |                |                  |                  |
| Adrenal insufficiency        |                |                  |                  |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 6 / 57 (10.53%)  | 2 / 58 (3.45%)   |
| occurrences (all)            | 0              | 6                | 2                |
| Autoimmune thyroiditis       |                |                  |                  |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)            | 0              | 0                | 0                |
| Hyperthyroidism              |                |                  |                  |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 9 / 57 (15.79%)  | 12 / 58 (20.69%) |
| occurrences (all)            | 0              | 10               | 12               |
| Hypophysitis                 |                |                  |                  |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 2 / 57 (3.51%)   | 0 / 58 (0.00%)   |
| occurrences (all)            | 0              | 2                | 0                |
| Hypopituitarism              |                |                  |                  |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)            | 0              | 0                | 1                |
| Hypothyroidism               |                |                  |                  |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 13 / 57 (22.81%) | 12 / 58 (20.69%) |
| occurrences (all)            | 0              | 16               | 13               |
| Thyroiditis                  |                |                  |                  |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 0 / 58 (0.00%)   |
| occurrences (all)            | 0              | 1                | 0                |

|                                                 |                |                  |                  |
|-------------------------------------------------|----------------|------------------|------------------|
| Inappropriate antidiuretic hormone secretion    |                |                  |                  |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                               | 0              | 0                | 0                |
| Musculoskeletal and connective tissue disorders |                |                  |                  |
| Arthralgia                                      |                |                  |                  |
| subjects affected / exposed                     | 2 / 3 (66.67%) | 15 / 57 (26.32%) | 10 / 58 (17.24%) |
| occurrences (all)                               | 2              | 16               | 15               |
| Back pain                                       |                |                  |                  |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 9 / 57 (15.79%)  | 6 / 58 (10.34%)  |
| occurrences (all)                               | 0              | 9                | 6                |
| Groin pain                                      |                |                  |                  |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 0 / 58 (0.00%)   |
| occurrences (all)                               | 0              | 1                | 0                |
| Hypercreatinaemia                               |                |                  |                  |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)                               | 0              | 0                | 1                |
| Joint swelling                                  |                |                  |                  |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 0 / 58 (0.00%)   |
| occurrences (all)                               | 0              | 1                | 0                |
| Muscular weakness                               |                |                  |                  |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 1 / 58 (1.72%)   |
| occurrences (all)                               | 0              | 1                | 1                |
| Muscle spasms                                   |                |                  |                  |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 4 / 58 (6.90%)   |
| occurrences (all)                               | 0              | 0                | 4                |
| Musculoskeletal chest pain                      |                |                  |                  |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)                               | 0              | 0                | 1                |
| Myalgia                                         |                |                  |                  |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 4 / 57 (7.02%)   | 5 / 58 (8.62%)   |
| occurrences (all)                               | 0              | 4                | 5                |
| Myositis                                        |                |                  |                  |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)                               | 0              | 0                | 0                |
| Neck pain                                       |                |                  |                  |

|                             |               |                |                |
|-----------------------------|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Pain in extremity           |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 4 / 57 (7.02%) | 4 / 58 (6.90%) |
| occurrences (all)           | 0             | 4              | 6              |
| Sacral pain                 |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Infections and infestations |               |                |                |
| Bronchitis                  |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 1 / 58 (1.72%) |
| occurrences (all)           | 0             | 1              | 1              |
| Campylobacter infection     |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| COVID-19                    |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 4 / 57 (7.02%) | 2 / 58 (3.45%) |
| occurrences (all)           | 0             | 4              | 2              |
| Candida infection           |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Cellulitis                  |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 1 / 58 (1.72%) |
| occurrences (all)           | 0             | 1              | 1              |
| Conjunctivitis              |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 1 / 58 (1.72%) |
| occurrences (all)           | 0             | 1              | 1              |
| Cystitis                    |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Diverticulitis              |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Eye infection bacterial     |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |

|                             |               |                |                |
|-----------------------------|---------------|----------------|----------------|
| Folliculitis                |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Gastroenteritis             |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 57 (3.51%) | 1 / 58 (1.72%) |
| occurrences (all)           | 0             | 2              | 1              |
| Hepatitis viral             |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Gastrointestinal infection  |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Herpes zoster               |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 1 / 58 (1.72%) |
| occurrences (all)           | 0             | 0              | 1              |
| Hordeolum                   |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Influenza                   |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Localised infection         |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 1 / 58 (1.72%) |
| occurrences (all)           | 0             | 1              | 1              |
| Mucosal infection           |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |
| Nasopharyngitis             |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 57 (3.51%) | 2 / 58 (3.45%) |
| occurrences (all)           | 0             | 2              | 2              |
| Oral candidiasis            |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 57 (1.75%) | 1 / 58 (1.72%) |
| occurrences (all)           | 0             | 1              | 1              |
| Norovirus infection         |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 57 (0.00%) | 0 / 58 (0.00%) |
| occurrences (all)           | 0             | 0              | 0              |

|                                    |                |                 |                 |
|------------------------------------|----------------|-----------------|-----------------|
| Pharyngitis                        |                |                 |                 |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)  | 2 / 58 (3.45%)  |
| occurrences (all)                  | 0              | 0               | 2               |
| Rash pustular                      |                |                 |                 |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)  | 0 / 58 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Pneumonia                          |                |                 |                 |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)  | 2 / 58 (3.45%)  |
| occurrences (all)                  | 0              | 0               | 2               |
| Soft tissue infection              |                |                 |                 |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 1 / 57 (1.75%)  | 4 / 58 (6.90%)  |
| occurrences (all)                  | 0              | 1               | 4               |
| Skin infection                     |                |                 |                 |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)  | 1 / 58 (1.72%)  |
| occurrences (all)                  | 0              | 0               | 1               |
| Spontaneous bacterial peritonitis  |                |                 |                 |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)  | 0 / 58 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Upper respiratory tract infection  |                |                 |                 |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)  | 1 / 58 (1.72%)  |
| occurrences (all)                  | 0              | 0               | 2               |
| Urinary tract infection            |                |                 |                 |
| subjects affected / exposed        | 1 / 3 (33.33%) | 6 / 57 (10.53%) | 6 / 58 (10.34%) |
| occurrences (all)                  | 1              | 8               | 7               |
| Staphylococcal infection           |                |                 |                 |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)  | 1 / 58 (1.72%)  |
| occurrences (all)                  | 0              | 0               | 1               |
| Vascular access site infection     |                |                 |                 |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 57 (0.00%)  | 0 / 58 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0               |
| Viral infection                    |                |                 |                 |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 1 / 57 (1.75%)  | 0 / 58 (0.00%)  |
| occurrences (all)                  | 0              | 1               | 0               |
| Metabolism and nutrition disorders |                |                 |                 |
| Decreased appetite                 |                |                 |                 |

|                             |                |                  |                  |
|-----------------------------|----------------|------------------|------------------|
| subjects affected / exposed | 0 / 3 (0.00%)  | 10 / 57 (17.54%) | 17 / 58 (29.31%) |
| occurrences (all)           | 0              | 11               | 18               |
| Dehydration                 |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 3 / 57 (5.26%)   | 2 / 58 (3.45%)   |
| occurrences (all)           | 0              | 3                | 2                |
| Electrolyte imbalance       |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Hyperglycaemia              |                |                  |                  |
| subjects affected / exposed | 1 / 3 (33.33%) | 5 / 57 (8.77%)   | 4 / 58 (6.90%)   |
| occurrences (all)           | 1              | 6                | 5                |
| Hypercalcaemia              |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Hyperkalaemia               |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 2 / 58 (3.45%)   |
| occurrences (all)           | 0              | 1                | 2                |
| Hypermagnesaemia            |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Hyperlipasaemia             |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 1                | 0                |
| Hyperuricaemia              |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 2 / 57 (3.51%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 3                | 0                |
| Hypernatraemia              |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)           | 0              | 0                | 1                |
| Hypoalbuminaemia            |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 1 / 58 (1.72%)   |
| occurrences (all)           | 0              | 0                | 1                |
| Hypocalcaemia               |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Hypochloraemia              |                |                  |                  |

|                             |                |                  |                  |
|-----------------------------|----------------|------------------|------------------|
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Hypokalaemia                |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 3 / 58 (5.17%)   |
| occurrences (all)           | 0              | 1                | 7                |
| Hypomagnesaemia             |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 57 (1.75%)   | 2 / 58 (3.45%)   |
| occurrences (all)           | 0              | 1                | 3                |
| Hyponatraemia               |                |                  |                  |
| subjects affected / exposed | 1 / 3 (33.33%) | 11 / 57 (19.30%) | 16 / 58 (27.59%) |
| occurrences (all)           | 4              | 19               | 30               |
| Hypovolaemia                |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Hypophosphataemia           |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Iron deficiency             |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |
| Malnutrition                |                |                  |                  |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 57 (0.00%)   | 0 / 58 (0.00%)   |
| occurrences (all)           | 0              | 0                | 0                |

| <b>Non-serious adverse events</b>                                   | Part 2A: Melanoma Arms Nivolumab Mono | Part 2A: Melanoma Arms BMS-986249 600mg IV Q8W | Part 2B: Cohort 1 (HCC) |
|---------------------------------------------------------------------|---------------------------------------|------------------------------------------------|-------------------------|
| Total subjects affected by non-serious adverse events               |                                       |                                                |                         |
| subjects affected / exposed                                         | 3 / 3 (100.00%)                       | 34 / 36 (94.44%)                               | 5 / 5 (100.00%)         |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                       |                                                |                         |
| Acrochordon                                                         |                                       |                                                |                         |
| subjects affected / exposed                                         | 0 / 3 (0.00%)                         | 0 / 36 (0.00%)                                 | 0 / 5 (0.00%)           |
| occurrences (all)                                                   | 0                                     | 0                                              | 0                       |
| Malignant neoplasm progression                                      |                                       |                                                |                         |
| subjects affected / exposed                                         | 0 / 3 (0.00%)                         | 0 / 36 (0.00%)                                 | 0 / 5 (0.00%)           |
| occurrences (all)                                                   | 0                                     | 0                                              | 0                       |
| Cancer pain                                                         |                                       |                                                |                         |

|                                                      |                |                 |               |
|------------------------------------------------------|----------------|-----------------|---------------|
| subjects affected / exposed                          | 0 / 3 (0.00%)  | 3 / 36 (8.33%)  | 0 / 5 (0.00%) |
| occurrences (all)                                    | 0              | 3               | 0             |
| Tumour pain                                          |                |                 |               |
| subjects affected / exposed                          | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%) |
| occurrences (all)                                    | 0              | 1               | 0             |
| Metastases to central nervous system                 |                |                 |               |
| subjects affected / exposed                          | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%) |
| occurrences (all)                                    | 0              | 0               | 0             |
| Vascular disorders                                   |                |                 |               |
| Deep vein thrombosis                                 |                |                 |               |
| subjects affected / exposed                          | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%) |
| occurrences (all)                                    | 0              | 0               | 0             |
| Haematoma                                            |                |                 |               |
| subjects affected / exposed                          | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%) |
| occurrences (all)                                    | 0              | 0               | 0             |
| Haemorrhage                                          |                |                 |               |
| subjects affected / exposed                          | 1 / 3 (33.33%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%) |
| occurrences (all)                                    | 1              | 0               | 0             |
| Hot flush                                            |                |                 |               |
| subjects affected / exposed                          | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%) |
| occurrences (all)                                    | 0              | 0               | 0             |
| Hypertension                                         |                |                 |               |
| subjects affected / exposed                          | 1 / 3 (33.33%) | 4 / 36 (11.11%) | 0 / 5 (0.00%) |
| occurrences (all)                                    | 1              | 4               | 0             |
| Hypotension                                          |                |                 |               |
| subjects affected / exposed                          | 0 / 3 (0.00%)  | 3 / 36 (8.33%)  | 0 / 5 (0.00%) |
| occurrences (all)                                    | 0              | 4               | 0             |
| Pallor                                               |                |                 |               |
| subjects affected / exposed                          | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%) |
| occurrences (all)                                    | 0              | 0               | 0             |
| Venous thrombosis                                    |                |                 |               |
| subjects affected / exposed                          | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%) |
| occurrences (all)                                    | 0              | 1               | 0             |
| General disorders and administration site conditions |                |                 |               |

|                                     |                |                 |                |
|-------------------------------------|----------------|-----------------|----------------|
| Asthenia                            |                |                 |                |
| subjects affected / exposed         | 1 / 3 (33.33%) | 3 / 36 (8.33%)  | 0 / 5 (0.00%)  |
| occurrences (all)                   | 1              | 3               | 0              |
| Application site reaction           |                |                 |                |
| subjects affected / exposed         | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0              |
| Axillary pain                       |                |                 |                |
| subjects affected / exposed         | 0 / 3 (0.00%)  | 2 / 36 (5.56%)  | 0 / 5 (0.00%)  |
| occurrences (all)                   | 0              | 2               | 0              |
| Chest discomfort                    |                |                 |                |
| subjects affected / exposed         | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0              |
| Chest pain                          |                |                 |                |
| subjects affected / exposed         | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)                   | 0              | 1               | 0              |
| Chills                              |                |                 |                |
| subjects affected / exposed         | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)                   | 0              | 2               | 0              |
| Complication associated with device |                |                 |                |
| subjects affected / exposed         | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0              |
| Device related thrombosis           |                |                 |                |
| subjects affected / exposed         | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0              |
| Gait disturbance                    |                |                 |                |
| subjects affected / exposed         | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0              |
| Fatigue                             |                |                 |                |
| subjects affected / exposed         | 0 / 3 (0.00%)  | 9 / 36 (25.00%) | 4 / 5 (80.00%) |
| occurrences (all)                   | 0              | 11              | 4              |
| Hernia pain                         |                |                 |                |
| subjects affected / exposed         | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0              |
| Injection site extravasation        |                |                 |                |
| subjects affected / exposed         | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                   | 0              | 0               | 0              |

|                              |                |                 |                |
|------------------------------|----------------|-----------------|----------------|
| Influenza like illness       |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 2 / 5 (40.00%) |
| occurrences (all)            | 0              | 2               | 2              |
| Localised oedema             |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Mucosal inflammation         |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 2 / 36 (5.56%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 2               | 0              |
| Malaise                      |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Non-cardiac chest pain       |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 1               | 0              |
| Oedema peripheral            |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 4 / 36 (11.11%) | 1 / 5 (20.00%) |
| occurrences (all)            | 0              | 5               | 1              |
| Pain                         |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Performance status decreased |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Peripheral swelling          |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Pyrexia                      |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 8 / 36 (22.22%) | 3 / 5 (60.00%) |
| occurrences (all)            | 0              | 15              | 4              |
| Swelling face                |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Xerosis                      |                |                 |                |
| subjects affected / exposed  | 1 / 3 (33.33%) | 4 / 36 (11.11%) | 0 / 5 (0.00%)  |
| occurrences (all)            | 1              | 4               | 0              |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                      |                                                                                                                                                             |                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| Temperature intolerance<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                                            | 0 / 3 (0.00%)<br>0                                                                                                                                   | 0 / 36 (0.00%)<br>0                                                                                                                                         | 0 / 5 (0.00%)<br>0                                                                                                         |
| Immune system disorders<br>Seasonal allergy<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                                                                                        | 0 / 3 (0.00%)<br>0                                                                                                                                   | 0 / 36 (0.00%)<br>0                                                                                                                                         | 0 / 5 (0.00%)<br>0                                                                                                         |
| Reproductive system and breast disorders<br>Heavy menstrual bleeding<br>subjects affected / exposed<br>occurrences (all)<br><br>Breast pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Vulvovaginal pruritus<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                       | 0 / 3 (0.00%)<br>0<br><br>0 / 3 (0.00%)<br>0<br><br>0 / 3 (0.00%)<br>0                                                                               | 0 / 36 (0.00%)<br>0<br><br>0 / 36 (0.00%)<br>0<br><br>0 / 36 (0.00%)<br>0                                                                                   | 0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0                                                     |
| Respiratory, thoracic and mediastinal disorders<br>Apnoea<br>subjects affected / exposed<br>occurrences (all)<br><br>Cough<br>subjects affected / exposed<br>occurrences (all)<br><br>Dysphonia<br>subjects affected / exposed<br>occurrences (all)<br><br>Dyspnoea<br>subjects affected / exposed<br>occurrences (all)<br><br>Nasal congestion<br>subjects affected / exposed<br>occurrences (all)<br><br>Hypoxia<br>subjects affected / exposed<br>occurrences (all) | 0 / 3 (0.00%)<br>0<br><br>0 / 3 (0.00%)<br>0<br><br>0 / 3 (0.00%)<br>0<br><br>0 / 3 (0.00%)<br>0<br><br>0 / 3 (0.00%)<br>0<br><br>0 / 3 (0.00%)<br>0 | 0 / 36 (0.00%)<br>0<br><br>4 / 36 (11.11%)<br>6<br><br>0 / 36 (0.00%)<br>0<br><br>3 / 36 (8.33%)<br>3<br><br>0 / 36 (0.00%)<br>0<br><br>0 / 36 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0 |

|                                         |               |                |                |
|-----------------------------------------|---------------|----------------|----------------|
| Haemoptysis                             |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                       | 0             | 0              | 0              |
| Oropharyngeal pain                      |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 1 / 5 (20.00%) |
| occurrences (all)                       | 0             | 1              | 1              |
| Pleural effusion                        |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                       | 0             | 0              | 0              |
| Pneumonitis                             |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 2 / 36 (5.56%) | 0 / 5 (0.00%)  |
| occurrences (all)                       | 0             | 2              | 0              |
| Pneumothorax                            |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                       | 0             | 0              | 0              |
| Pulmonary embolism                      |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%)  |
| occurrences (all)                       | 0             | 1              | 0              |
| Rhinitis allergic                       |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                       | 0             | 0              | 0              |
| Rhinorrhoea                             |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                       | 0             | 0              | 0              |
| Upper-airway cough syndrome             |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                       | 0             | 0              | 0              |
| Wheezing                                |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                       | 0             | 0              | 0              |
| Psychiatric disorders                   |               |                |                |
| Adjustment disorder with depressed mood |               |                |                |
| subjects affected / exposed             | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                       | 0             | 0              | 0              |
| Affective disorder                      |               |                |                |

|                                    |                |                  |                |
|------------------------------------|----------------|------------------|----------------|
| subjects affected / exposed        | 0 / 3 (0.00%)  | 1 / 36 (2.78%)   | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 1                | 0              |
| Anxiety                            |                |                  |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 2 / 36 (5.56%)   | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 2                | 0              |
| Depression                         |                |                  |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0                | 0              |
| Disorientation                     |                |                  |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0                | 0              |
| Insomnia                           |                |                  |                |
| subjects affected / exposed        | 1 / 3 (33.33%) | 2 / 36 (5.56%)   | 0 / 5 (0.00%)  |
| occurrences (all)                  | 1              | 2                | 0              |
| Libido decreased                   |                |                  |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0                | 0              |
| Mental status changes              |                |                  |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0                | 0              |
| Panic attack                       |                |                  |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0                | 0              |
| Investigations                     |                |                  |                |
| Ammonia increased                  |                |                  |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0                | 0              |
| Alanine aminotransferase increased |                |                  |                |
| subjects affected / exposed        | 1 / 3 (33.33%) | 14 / 36 (38.89%) | 2 / 5 (40.00%) |
| occurrences (all)                  | 1              | 21               | 2              |
| Amylase increased                  |                |                  |                |
| subjects affected / exposed        | 2 / 3 (66.67%) | 6 / 36 (16.67%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 2              | 11               | 0              |
| Blood albumin decreased            |                |                  |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 1 / 36 (2.78%)   | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 1                | 0              |

|                                        |                |                  |                |
|----------------------------------------|----------------|------------------|----------------|
| Aspartate aminotransferase increased   |                |                  |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 10 / 36 (27.78%) | 2 / 5 (40.00%) |
| occurrences (all)                      | 0              | 12               | 2              |
| Blood bilirubin increased              |                |                  |                |
| subjects affected / exposed            | 1 / 3 (33.33%) | 2 / 36 (5.56%)   | 2 / 5 (40.00%) |
| occurrences (all)                      | 5              | 3                | 3              |
| Blood alkaline phosphatase increased   |                |                  |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 1 / 36 (2.78%)   | 1 / 5 (20.00%) |
| occurrences (all)                      | 0              | 1                | 1              |
| Blood calcium decreased                |                |                  |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                      | 0              | 0                | 0              |
| Blood calcium increased                |                |                  |                |
| subjects affected / exposed            | 1 / 3 (33.33%) | 2 / 36 (5.56%)   | 0 / 5 (0.00%)  |
| occurrences (all)                      | 1              | 3                | 0              |
| Blood cholesterol increased            |                |                  |                |
| subjects affected / exposed            | 1 / 3 (33.33%) | 1 / 36 (2.78%)   | 0 / 5 (0.00%)  |
| occurrences (all)                      | 1              | 1                | 0              |
| Blood creatine phosphokinase increased |                |                  |                |
| subjects affected / exposed            | 1 / 3 (33.33%) | 2 / 36 (5.56%)   | 0 / 5 (0.00%)  |
| occurrences (all)                      | 1              | 2                | 0              |
| Blood creatinine increased             |                |                  |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 4 / 36 (11.11%)  | 1 / 5 (20.00%) |
| occurrences (all)                      | 0              | 4                | 1              |
| Blood glucose decreased                |                |                  |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                      | 0              | 0                | 0              |
| Blood lactic acid increased            |                |                  |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                      | 0              | 0                | 0              |
| Blood glucose increased                |                |                  |                |
| subjects affected / exposed            | 1 / 3 (33.33%) | 1 / 36 (2.78%)   | 0 / 5 (0.00%)  |
| occurrences (all)                      | 1              | 1                | 0              |
| Blood magnesium decreased              |                |                  |                |

|                                             |                |                |                |
|---------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 2 / 36 (5.56%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 2              | 0              |
| Blood phosphorus increased                  |                |                |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0              | 0              |
| Blood potassium decreased                   |                |                |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 2 / 36 (5.56%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 2              | 0              |
| Blood prolactin increased                   |                |                |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0              | 0              |
| Blood sodium decreased                      |                |                |                |
| subjects affected / exposed                 | 1 / 3 (33.33%) | 1 / 36 (2.78%) | 1 / 5 (20.00%) |
| occurrences (all)                           | 2              | 1              | 1              |
| Blood thyroid stimulating hormone decreased |                |                |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0              | 0              |
| Blood thyroid stimulating hormone increased |                |                |                |
| subjects affected / exposed                 | 1 / 3 (33.33%) | 2 / 36 (5.56%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 1              | 2              | 0              |
| Blood uric acid increased                   |                |                |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0              | 0              |
| C-reactive protein increased                |                |                |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0              | 0              |
| Cardiac murmur                              |                |                |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0              | 0              |
| Gamma-glutamyltransferase increased         |                |                |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0              | 0              |
| Haemoglobin decreased                       |                |                |                |

|                                          |                |                 |                |
|------------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed              | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)                        | 0              | 1               | 0              |
| International normalised ratio increased |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                        | 0              | 0               | 0              |
| Lipase increased                         |                |                 |                |
| subjects affected / exposed              | 1 / 3 (33.33%) | 7 / 36 (19.44%) | 0 / 5 (0.00%)  |
| occurrences (all)                        | 5              | 10              | 0              |
| Liver function test increased            |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                        | 0              | 0               | 0              |
| Neutrophil count decreased               |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                        | 0              | 0               | 0              |
| Platelet count decreased                 |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 2 / 36 (5.56%)  | 1 / 5 (20.00%) |
| occurrences (all)                        | 0              | 2               | 1              |
| Troponin I increased                     |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)                        | 0              | 1               | 0              |
| Transaminases increased                  |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)                        | 0              | 1               | 0              |
| Troponin increased                       |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)                        | 0              | 1               | 0              |
| Urine phosphorus increased               |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                        | 0              | 0               | 0              |
| Urine calcium increased                  |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                        | 0              | 0               | 0              |
| Weight decreased                         |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 8 / 36 (22.22%) | 0 / 5 (0.00%)  |
| occurrences (all)                        | 0              | 9               | 0              |

|                                                                                      |                    |                     |                    |
|--------------------------------------------------------------------------------------|--------------------|---------------------|--------------------|
| White blood cell count decreased<br>subjects affected / exposed<br>occurrences (all) | 0 / 3 (0.00%)<br>0 | 0 / 36 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0 |
| White blood cell count increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 3 (0.00%)<br>0 | 0 / 36 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0 |
| Injury, poisoning and procedural complications                                       |                    |                     |                    |
| Fall                                                                                 |                    |                     |                    |
| subjects affected / exposed                                                          | 0 / 3 (0.00%)      | 0 / 36 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                                                    | 0                  | 0                   | 0                  |
| Femur fracture                                                                       |                    |                     |                    |
| subjects affected / exposed                                                          | 0 / 3 (0.00%)      | 0 / 36 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                                                    | 0                  | 0                   | 0                  |
| Infusion related reaction                                                            |                    |                     |                    |
| subjects affected / exposed                                                          | 0 / 3 (0.00%)      | 1 / 36 (2.78%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                                                    | 0                  | 1                   | 0                  |
| Muscle strain                                                                        |                    |                     |                    |
| subjects affected / exposed                                                          | 0 / 3 (0.00%)      | 0 / 36 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                                                    | 0                  | 0                   | 0                  |
| Lip injury                                                                           |                    |                     |                    |
| subjects affected / exposed                                                          | 0 / 3 (0.00%)      | 0 / 36 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                                                    | 0                  | 0                   | 0                  |
| Procedural pain                                                                      |                    |                     |                    |
| subjects affected / exposed                                                          | 0 / 3 (0.00%)      | 0 / 36 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                                                    | 0                  | 0                   | 0                  |
| Rib fracture                                                                         |                    |                     |                    |
| subjects affected / exposed                                                          | 0 / 3 (0.00%)      | 0 / 36 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                                                    | 0                  | 0                   | 0                  |
| Skin abrasion                                                                        |                    |                     |                    |
| subjects affected / exposed                                                          | 0 / 3 (0.00%)      | 0 / 36 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                                                    | 0                  | 0                   | 0                  |
| Tooth fracture                                                                       |                    |                     |                    |
| subjects affected / exposed                                                          | 0 / 3 (0.00%)      | 0 / 36 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                                                    | 0                  | 0                   | 0                  |
| Vascular access site erythema                                                        |                    |                     |                    |

|                             |               |                |                |
|-----------------------------|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Wound secretion             |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Cardiac disorders           |               |                |                |
| Atrial fibrillation         |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Palpitations                |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 36 (5.56%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 2              | 0              |
| Pericardial effusion        |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Sinus bradycardia           |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Sinus tachycardia           |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Tachycardia                 |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 1 / 5 (20.00%) |
| occurrences (all)           | 0             | 1              | 1              |
| Nervous system disorders    |               |                |                |
| Aphasia                     |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 1              | 0              |
| Cognitive disorder          |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Dysarthria                  |               |                |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Dizziness                   |               |                |                |

|                               |                |                 |                |
|-------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed   | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)             | 0              | 1               | 0              |
| Headache                      |                |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%)  | 5 / 36 (13.89%) | 2 / 5 (40.00%) |
| occurrences (all)             | 0              | 5               | 2              |
| Dysgeusia                     |                |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 1 / 5 (20.00%) |
| occurrences (all)             | 0              | 1               | 1              |
| Hyperaesthesia                |                |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)             | 0              | 0               | 0              |
| Lethargy                      |                |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)             | 0              | 0               | 0              |
| Neuralgia                     |                |                 |                |
| subjects affected / exposed   | 1 / 3 (33.33%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)             | 1              | 0               | 0              |
| Neuropathy peripheral         |                |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)             | 0              | 0               | 0              |
| Paraesthesia                  |                |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)             | 0              | 0               | 0              |
| Parkinson's disease           |                |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 1 / 5 (20.00%) |
| occurrences (all)             | 0              | 0               | 1              |
| Peripheral sensory neuropathy |                |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)             | 0              | 0               | 0              |
| Peripheral motor neuropathy   |                |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)             | 0              | 0               | 0              |
| Post herpetic neuralgia       |                |                 |                |
| subjects affected / exposed   | 1 / 3 (33.33%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)             | 1              | 0               | 0              |
| Restless legs syndrome        |                |                 |                |

|                                      |                |                  |                |
|--------------------------------------|----------------|------------------|----------------|
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                    | 0              | 0                | 0              |
| Radiculopathy                        |                |                  |                |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                    | 0              | 0                | 0              |
| Somnolence                           |                |                  |                |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                    | 0              | 0                | 0              |
| Sciatica                             |                |                  |                |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                    | 0              | 0                | 0              |
| Tension headache                     |                |                  |                |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 1 / 36 (2.78%)   | 0 / 5 (0.00%)  |
| occurrences (all)                    | 0              | 1                | 0              |
| Tremor                               |                |                  |                |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 1 / 5 (20.00%) |
| occurrences (all)                    | 0              | 0                | 1              |
| Blood and lymphatic system disorders |                |                  |                |
| Anaemia                              |                |                  |                |
| subjects affected / exposed          | 2 / 3 (66.67%) | 13 / 36 (36.11%) | 1 / 5 (20.00%) |
| occurrences (all)                    | 2              | 19               | 1              |
| Eosinophilia                         |                |                  |                |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 3 / 36 (8.33%)   | 0 / 5 (0.00%)  |
| occurrences (all)                    | 0              | 4                | 0              |
| Iron deficiency anaemia              |                |                  |                |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                    | 0              | 0                | 0              |
| Leukocytosis                         |                |                  |                |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                    | 0              | 0                | 0              |
| Lymphopenia                          |                |                  |                |
| subjects affected / exposed          | 0 / 3 (0.00%)  | 2 / 36 (5.56%)   | 0 / 5 (0.00%)  |
| occurrences (all)                    | 0              | 2                | 0              |
| Thrombocytopenia                     |                |                  |                |
| subjects affected / exposed          | 1 / 3 (33.33%) | 0 / 36 (0.00%)   | 1 / 5 (20.00%) |
| occurrences (all)                    | 1              | 0                | 1              |

|                                                                          |                     |                     |                    |
|--------------------------------------------------------------------------|---------------------|---------------------|--------------------|
| Neutropenia<br>subjects affected / exposed<br>occurrences (all)          | 1 / 3 (33.33%)<br>1 | 2 / 36 (5.56%)<br>2 | 0 / 5 (0.00%)<br>0 |
| Ear and labyrinth disorders                                              |                     |                     |                    |
| Ear pain<br>subjects affected / exposed<br>occurrences (all)             | 0 / 3 (0.00%)<br>0  | 0 / 36 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0 |
| Hypoacusis<br>subjects affected / exposed<br>occurrences (all)           | 0 / 3 (0.00%)<br>0  | 0 / 36 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0 |
| Vertigo<br>subjects affected / exposed<br>occurrences (all)              | 0 / 3 (0.00%)<br>0  | 1 / 36 (2.78%)<br>1 | 0 / 5 (0.00%)<br>0 |
| Eye disorders                                                            |                     |                     |                    |
| Dry eye<br>subjects affected / exposed<br>occurrences (all)              | 0 / 3 (0.00%)<br>0  | 0 / 36 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0 |
| Iridocyclitis<br>subjects affected / exposed<br>occurrences (all)        | 0 / 3 (0.00%)<br>0  | 0 / 36 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0 |
| Eyelid irritation<br>subjects affected / exposed<br>occurrences (all)    | 0 / 3 (0.00%)<br>0  | 0 / 36 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0 |
| Vision blurred<br>subjects affected / exposed<br>occurrences (all)       | 0 / 3 (0.00%)<br>0  | 0 / 36 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0 |
| Swelling of eyelid<br>subjects affected / exposed<br>occurrences (all)   | 0 / 3 (0.00%)<br>0  | 0 / 36 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0 |
| Gastrointestinal disorders                                               |                     |                     |                    |
| Abdominal discomfort<br>subjects affected / exposed<br>occurrences (all) | 0 / 3 (0.00%)<br>0  | 0 / 36 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0 |
| Abdominal distension<br>subjects affected / exposed<br>occurrences (all) | 0 / 3 (0.00%)<br>0  | 1 / 36 (2.78%)<br>1 | 0 / 5 (0.00%)<br>0 |
| Abdominal pain                                                           |                     |                     |                    |

|                             |                |                  |                |
|-----------------------------|----------------|------------------|----------------|
| subjects affected / exposed | 0 / 3 (0.00%)  | 4 / 36 (11.11%)  | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 4                | 0              |
| Abdominal pain lower        |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 0                | 0              |
| Abdominal pain upper        |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 4 / 36 (11.11%)  | 1 / 5 (20.00%) |
| occurrences (all)           | 0              | 4                | 2              |
| Ascites                     |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 36 (2.78%)   | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 1                | 0              |
| Colitis                     |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 3 / 36 (8.33%)   | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 4                | 0              |
| Constipation                |                |                  |                |
| subjects affected / exposed | 2 / 3 (66.67%) | 5 / 36 (13.89%)  | 1 / 5 (20.00%) |
| occurrences (all)           | 2              | 6                | 1              |
| Diarrhoea                   |                |                  |                |
| subjects affected / exposed | 1 / 3 (33.33%) | 15 / 36 (41.67%) | 2 / 5 (40.00%) |
| occurrences (all)           | 1              | 33               | 4              |
| Dyspepsia                   |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 36 (2.78%)   | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 1                | 0              |
| Dry mouth                   |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 2 / 36 (5.56%)   | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 2                | 0              |
| Dysphagia                   |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 36 (2.78%)   | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 1                | 0              |
| Enteritis                   |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 36 (2.78%)   | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 1                | 0              |
| Flatulence                  |                |                  |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 36 (2.78%)   | 1 / 5 (20.00%) |
| occurrences (all)           | 0              | 1                | 1              |
| Frequent bowel movements    |                |                  |                |

|                                    |                |                 |                |
|------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Gastritis                          |                |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 2 / 36 (5.56%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 2               | 0              |
| Gastrointestinal motility disorder |                |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Gastrointestinal haemorrhage       |                |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Gastrooesophageal reflux disease   |                |                 |                |
| subjects affected / exposed        | 1 / 3 (33.33%) | 2 / 36 (5.56%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 1              | 2               | 0              |
| Immune-mediated enterocolitis      |                |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 2 / 36 (5.56%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 3               | 0              |
| Impaired gastric emptying          |                |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Mouth ulceration                   |                |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Nausea                             |                |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 9 / 36 (25.00%) | 1 / 5 (20.00%) |
| occurrences (all)                  | 0              | 11              | 1              |
| Oesophageal varices haemorrhage    |                |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Oral dysaesthesia                  |                |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Proctalgia                         |                |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0              | 0               | 0              |
| Rectal haemorrhage                 |                |                 |                |

|                                                                                                    |                    |                      |                     |
|----------------------------------------------------------------------------------------------------|--------------------|----------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                                                   | 0 / 3 (0.00%)<br>0 | 0 / 36 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Stomatitis<br>subjects affected / exposed<br>occurrences (all)                                     | 0 / 3 (0.00%)<br>0 | 2 / 36 (5.56%)<br>3  | 1 / 5 (20.00%)<br>1 |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)                                       | 0 / 3 (0.00%)<br>0 | 7 / 36 (19.44%)<br>9 | 0 / 5 (0.00%)<br>0  |
| Hepatobiliary disorders<br>Biliary obstruction<br>subjects affected / exposed<br>occurrences (all) | 0 / 3 (0.00%)<br>0 | 0 / 36 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Autoimmune hepatitis<br>subjects affected / exposed<br>occurrences (all)                           | 0 / 3 (0.00%)<br>0 | 1 / 36 (2.78%)<br>1  | 0 / 5 (0.00%)<br>0  |
| Hepatitis<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 3 (0.00%)<br>0 | 2 / 36 (5.56%)<br>4  | 0 / 5 (0.00%)<br>0  |
| Hepatic failure<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 3 (0.00%)<br>0 | 0 / 36 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Hyperbilirubinaemia<br>subjects affected / exposed<br>occurrences (all)                            | 0 / 3 (0.00%)<br>0 | 0 / 36 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Hypertransaminaemia<br>subjects affected / exposed<br>occurrences (all)                            | 0 / 3 (0.00%)<br>0 | 5 / 36 (13.89%)<br>5 | 0 / 5 (0.00%)<br>0  |
| Immune-mediated hepatitis<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 3 (0.00%)<br>0 | 0 / 36 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Jaundice cholestatic<br>subjects affected / exposed<br>occurrences (all)                           | 0 / 3 (0.00%)<br>0 | 0 / 36 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Portal hypertension<br>subjects affected / exposed<br>occurrences (all)                            | 0 / 3 (0.00%)<br>0 | 0 / 36 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |

|                                        |               |                |                |
|----------------------------------------|---------------|----------------|----------------|
| Skin and subcutaneous tissue disorders |               |                |                |
| Alopecia                               |               |                |                |
| subjects affected / exposed            | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%)  |
| occurrences (all)                      | 0             | 1              | 0              |
| Acquired porokeratosis                 |               |                |                |
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                      | 0             | 0              | 0              |
| Dermatitis acneiform                   |               |                |                |
| subjects affected / exposed            | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 0 / 5 (0.00%)  |
| occurrences (all)                      | 0             | 1              | 0              |
| Drug eruption                          |               |                |                |
| subjects affected / exposed            | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 1 / 5 (20.00%) |
| occurrences (all)                      | 0             | 1              | 1              |
| Dry skin                               |               |                |                |
| subjects affected / exposed            | 0 / 3 (0.00%) | 1 / 36 (2.78%) | 1 / 5 (20.00%) |
| occurrences (all)                      | 0             | 1              | 1              |
| Eczema                                 |               |                |                |
| subjects affected / exposed            | 0 / 3 (0.00%) | 3 / 36 (8.33%) | 1 / 5 (20.00%) |
| occurrences (all)                      | 0             | 4              | 1              |
| Erythema                               |               |                |                |
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                      | 0             | 0              | 0              |
| Ecchymosis                             |               |                |                |
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                      | 0             | 0              | 0              |
| Night sweats                           |               |                |                |
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                      | 0             | 0              | 0              |
| Keloid scar                            |               |                |                |
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all)                      | 0             | 0              | 1              |
| Leukoplakia                            |               |                |                |
| subjects affected / exposed            | 0 / 3 (0.00%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                      | 0             | 0              | 0              |
| Rash                                   |               |                |                |

|                                             |                |                  |                |
|---------------------------------------------|----------------|------------------|----------------|
| subjects affected / exposed                 | 1 / 3 (33.33%) | 2 / 36 (5.56%)   | 0 / 5 (0.00%)  |
| occurrences (all)                           | 1              | 2                | 0              |
| Pruritus                                    |                |                  |                |
| subjects affected / exposed                 | 1 / 3 (33.33%) | 10 / 36 (27.78%) | 1 / 5 (20.00%) |
| occurrences (all)                           | 2              | 11               | 1              |
| Palmar-plantar erythrodysaesthesia syndrome |                |                  |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0                | 0              |
| Rash maculo-papular                         |                |                  |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 6 / 36 (16.67%)  | 2 / 5 (40.00%) |
| occurrences (all)                           | 0              | 7                | 2              |
| Rash macular                                |                |                  |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0                | 0              |
| Rash erythematous                           |                |                  |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 1 / 36 (2.78%)   | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 1                | 0              |
| Rash pruritic                               |                |                  |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0                | 0              |
| Rash vesicular                              |                |                  |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0                | 0              |
| Transient acantholytic dermatosis           |                |                  |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 0 / 36 (0.00%)   | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0                | 0              |
| Skin hypopigmentation                       |                |                  |                |
| subjects affected / exposed                 | 1 / 3 (33.33%) | 1 / 36 (2.78%)   | 0 / 5 (0.00%)  |
| occurrences (all)                           | 1              | 1                | 0              |
| Urticaria                                   |                |                  |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 2 / 36 (5.56%)   | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 2                | 0              |
| Vitiligo                                    |                |                  |                |
| subjects affected / exposed                 | 0 / 3 (0.00%)  | 4 / 36 (11.11%)  | 1 / 5 (20.00%) |
| occurrences (all)                           | 0              | 4                | 1              |

|                              |                |                 |                |
|------------------------------|----------------|-----------------|----------------|
| Renal and urinary disorders  |                |                 |                |
| Acute kidney injury          |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Pollakiuria                  |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Proteinuria                  |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Haematuria                   |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Tubulointerstitial nephritis |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Endocrine disorders          |                |                 |                |
| Adrenal insufficiency        |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 2 / 36 (5.56%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 2               | 0              |
| Autoimmune thyroiditis       |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 0               | 0              |
| Hyperthyroidism              |                |                 |                |
| subjects affected / exposed  | 1 / 3 (33.33%) | 1 / 36 (2.78%)  | 1 / 5 (20.00%) |
| occurrences (all)            | 1              | 1               | 1              |
| Hypophysitis                 |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 3 / 36 (8.33%)  | 1 / 5 (20.00%) |
| occurrences (all)            | 0              | 3               | 1              |
| Hypopituitarism              |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)            | 0              | 1               | 0              |
| Hypothyroidism               |                |                 |                |
| subjects affected / exposed  | 0 / 3 (0.00%)  | 8 / 36 (22.22%) | 1 / 5 (20.00%) |
| occurrences (all)            | 0              | 8               | 1              |
| Thyroiditis                  |                |                 |                |

|                                                 |                |                 |               |
|-------------------------------------------------|----------------|-----------------|---------------|
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 4 / 36 (11.11%) | 0 / 5 (0.00%) |
| occurrences (all)                               | 0              | 4               | 0             |
| Inappropriate antidiuretic hormone secretion    |                |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%) |
| occurrences (all)                               | 0              | 0               | 0             |
| Musculoskeletal and connective tissue disorders |                |                 |               |
| Arthralgia                                      |                |                 |               |
| subjects affected / exposed                     | 1 / 3 (33.33%) | 5 / 36 (13.89%) | 0 / 5 (0.00%) |
| occurrences (all)                               | 1              | 6               | 0             |
| Back pain                                       |                |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 3 / 36 (8.33%)  | 0 / 5 (0.00%) |
| occurrences (all)                               | 0              | 3               | 0             |
| Groin pain                                      |                |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%) |
| occurrences (all)                               | 0              | 0               | 0             |
| Hypercreatinaemia                               |                |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 36 (0.00%)  | 0 / 5 (0.00%) |
| occurrences (all)                               | 0              | 0               | 0             |
| Joint swelling                                  |                |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%) |
| occurrences (all)                               | 0              | 1               | 0             |
| Muscular weakness                               |                |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 2 / 36 (5.56%)  | 0 / 5 (0.00%) |
| occurrences (all)                               | 0              | 2               | 0             |
| Muscle spasms                                   |                |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 36 (2.78%)  | 0 / 5 (0.00%) |
| occurrences (all)                               | 0              | 1               | 0             |
| Musculoskeletal chest pain                      |                |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 2 / 36 (5.56%)  | 0 / 5 (0.00%) |
| occurrences (all)                               | 0              | 2               | 0             |
| Myalgia                                         |                |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 8 / 36 (22.22%) | 0 / 5 (0.00%) |
| occurrences (all)                               | 0              | 9               | 0             |
| Myositis                                        |                |                 |               |

|                             |               |                 |                |
|-----------------------------|---------------|-----------------|----------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0               | 0              |
| Neck pain                   |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0               | 0              |
| Pain in extremity           |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 3 / 36 (8.33%)  | 1 / 5 (20.00%) |
| occurrences (all)           | 0             | 4               | 1              |
| Sacral pain                 |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0               | 0              |
| Infections and infestations |               |                 |                |
| Bronchitis                  |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 1               | 0              |
| Campylobacter infection     |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0               | 0              |
| COVID-19                    |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 7 / 36 (19.44%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 7               | 0              |
| Candida infection           |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0               | 0              |
| Cellulitis                  |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 1               | 0              |
| Conjunctivitis              |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 3 / 36 (8.33%)  | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 4               | 0              |
| Cystitis                    |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 1               | 0              |
| Diverticulitis              |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)           | 0             | 0               | 0              |

|                             |                |                |               |
|-----------------------------|----------------|----------------|---------------|
| Eye infection bacterial     |                |                |               |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Folliculitis                |                |                |               |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Gastroenteritis             |                |                |               |
| subjects affected / exposed | 0 / 3 (0.00%)  | 2 / 36 (5.56%) | 0 / 5 (0.00%) |
| occurrences (all)           | 0              | 2              | 0             |
| Hepatitis viral             |                |                |               |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Gastrointestinal infection  |                |                |               |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Herpes zoster               |                |                |               |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)           | 1              | 0              | 0             |
| Hordeolum                   |                |                |               |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences (all)           | 0              | 1              | 0             |
| Influenza                   |                |                |               |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Localised infection         |                |                |               |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 36 (2.78%) | 0 / 5 (0.00%) |
| occurrences (all)           | 0              | 1              | 0             |
| Mucosal infection           |                |                |               |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Nasopharyngitis             |                |                |               |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)           | 0              | 0              | 0             |
| Oral candidiasis            |                |                |               |
| subjects affected / exposed | 0 / 3 (0.00%)  | 2 / 36 (5.56%) | 0 / 5 (0.00%) |
| occurrences (all)           | 0              | 2              | 0             |

|                                   |                |                |                |
|-----------------------------------|----------------|----------------|----------------|
| Norovirus infection               |                |                |                |
| subjects affected / exposed       | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                 | 0              | 0              | 0              |
| Pharyngitis                       |                |                |                |
| subjects affected / exposed       | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                 | 0              | 0              | 0              |
| Rash pustular                     |                |                |                |
| subjects affected / exposed       | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                 | 0              | 0              | 0              |
| Pneumonia                         |                |                |                |
| subjects affected / exposed       | 0 / 3 (0.00%)  | 2 / 36 (5.56%) | 0 / 5 (0.00%)  |
| occurrences (all)                 | 0              | 2              | 0              |
| Soft tissue infection             |                |                |                |
| subjects affected / exposed       | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                 | 0              | 0              | 0              |
| Skin infection                    |                |                |                |
| subjects affected / exposed       | 1 / 3 (33.33%) | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                 | 1              | 0              | 0              |
| Spontaneous bacterial peritonitis |                |                |                |
| subjects affected / exposed       | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                 | 0              | 0              | 0              |
| Upper respiratory tract infection |                |                |                |
| subjects affected / exposed       | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                 | 0              | 0              | 0              |
| Urinary tract infection           |                |                |                |
| subjects affected / exposed       | 0 / 3 (0.00%)  | 3 / 36 (8.33%) | 1 / 5 (20.00%) |
| occurrences (all)                 | 0              | 4              | 2              |
| Staphylococcal infection          |                |                |                |
| subjects affected / exposed       | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                 | 0              | 0              | 0              |
| Vascular access site infection    |                |                |                |
| subjects affected / exposed       | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                 | 0              | 0              | 0              |
| Viral infection                   |                |                |                |
| subjects affected / exposed       | 0 / 3 (0.00%)  | 1 / 36 (2.78%) | 1 / 5 (20.00%) |
| occurrences (all)                 | 0              | 1              | 1              |

|                                    |               |                 |                |
|------------------------------------|---------------|-----------------|----------------|
| Metabolism and nutrition disorders |               |                 |                |
| Decreased appetite                 |               |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%) | 7 / 36 (19.44%) | 1 / 5 (20.00%) |
| occurrences (all)                  | 0             | 7               | 1              |
| Dehydration                        |               |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%) | 4 / 36 (11.11%) | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0             | 5               | 0              |
| Electrolyte imbalance              |               |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0              |
| Hyperglycaemia                     |               |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%) | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0             | 1               | 0              |
| Hypercalcaemia                     |               |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0              |
| Hyperkalaemia                      |               |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0              |
| Hypermagnesaemia                   |               |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0              |
| Hyperlipasaemia                    |               |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%) | 1 / 36 (2.78%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0             | 2               | 0              |
| Hyperuricaemia                     |               |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0              |
| Hypernatraemia                     |               |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0              |
| Hypoalbuminaemia                   |               |                 |                |
| subjects affected / exposed        | 0 / 3 (0.00%) | 0 / 36 (0.00%)  | 0 / 5 (0.00%)  |
| occurrences (all)                  | 0             | 0               | 0              |
| Hypocalcaemia                      |               |                 |                |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 36 (2.78%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 1              | 0              |
| Hypochloraemia              |                |                |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 36 (2.78%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 1              | 0              |
| Hypokalaemia                |                |                |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 36 (2.78%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 1              | 0              |
| Hypomagnesaemia             |                |                |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0              |
| Hyponatraemia               |                |                |                |
| subjects affected / exposed | 2 / 3 (66.67%) | 3 / 36 (8.33%) | 1 / 5 (20.00%) |
| occurrences (all)           | 4              | 4              | 2              |
| Hypovolaemia                |                |                |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0              |
| Hypophosphataemia           |                |                |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 36 (2.78%) | 1 / 5 (20.00%) |
| occurrences (all)           | 0              | 1              | 1              |
| Iron deficiency             |                |                |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0              |
| Malnutrition                |                |                |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 36 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0              |

| <b>Non-serious adverse events</b>                                   | Part 2B: Cohort 2<br>(Metastatic CRPC) | Part 2B: Cohort 3<br>(Unresectable TNBC) |  |
|---------------------------------------------------------------------|----------------------------------------|------------------------------------------|--|
| Total subjects affected by non-serious adverse events               |                                        |                                          |  |
| subjects affected / exposed                                         | 39 / 41 (95.12%)                       | 45 / 45 (100.00%)                        |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                        |                                          |  |
| Acrochordon                                                         |                                        |                                          |  |
| subjects affected / exposed                                         | 0 / 41 (0.00%)                         | 0 / 45 (0.00%)                           |  |
| occurrences (all)                                                   | 0                                      | 0                                        |  |
| Malignant neoplasm progression                                      |                                        |                                          |  |

|                                      |                 |                |  |
|--------------------------------------|-----------------|----------------|--|
| subjects affected / exposed          | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |  |
| occurrences (all)                    | 0               | 0              |  |
| Cancer pain                          |                 |                |  |
| subjects affected / exposed          | 2 / 41 (4.88%)  | 2 / 45 (4.44%) |  |
| occurrences (all)                    | 2               | 3              |  |
| Tumour pain                          |                 |                |  |
| subjects affected / exposed          | 1 / 41 (2.44%)  | 0 / 45 (0.00%) |  |
| occurrences (all)                    | 1               | 0              |  |
| Metastases to central nervous system |                 |                |  |
| subjects affected / exposed          | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |  |
| occurrences (all)                    | 0               | 0              |  |
| Vascular disorders                   |                 |                |  |
| Deep vein thrombosis                 |                 |                |  |
| subjects affected / exposed          | 1 / 41 (2.44%)  | 0 / 45 (0.00%) |  |
| occurrences (all)                    | 1               | 0              |  |
| Haematoma                            |                 |                |  |
| subjects affected / exposed          | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |  |
| occurrences (all)                    | 0               | 0              |  |
| Haemorrhage                          |                 |                |  |
| subjects affected / exposed          | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |  |
| occurrences (all)                    | 0               | 0              |  |
| Hot flush                            |                 |                |  |
| subjects affected / exposed          | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |  |
| occurrences (all)                    | 0               | 0              |  |
| Hypertension                         |                 |                |  |
| subjects affected / exposed          | 5 / 41 (12.20%) | 2 / 45 (4.44%) |  |
| occurrences (all)                    | 5               | 2              |  |
| Hypotension                          |                 |                |  |
| subjects affected / exposed          | 1 / 41 (2.44%)  | 0 / 45 (0.00%) |  |
| occurrences (all)                    | 2               | 0              |  |
| Pallor                               |                 |                |  |
| subjects affected / exposed          | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |  |
| occurrences (all)                    | 0               | 0              |  |
| Venous thrombosis                    |                 |                |  |

|                                                      |                  |                  |  |
|------------------------------------------------------|------------------|------------------|--|
| subjects affected / exposed                          | 0 / 41 (0.00%)   | 1 / 45 (2.22%)   |  |
| occurrences (all)                                    | 0                | 1                |  |
| General disorders and administration site conditions |                  |                  |  |
| Asthenia                                             |                  |                  |  |
| subjects affected / exposed                          | 3 / 41 (7.32%)   | 7 / 45 (15.56%)  |  |
| occurrences (all)                                    | 3                | 7                |  |
| Application site reaction                            |                  |                  |  |
| subjects affected / exposed                          | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                                    | 0                | 0                |  |
| Axillary pain                                        |                  |                  |  |
| subjects affected / exposed                          | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                                    | 0                | 0                |  |
| Chest discomfort                                     |                  |                  |  |
| subjects affected / exposed                          | 1 / 41 (2.44%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                                    | 1                | 0                |  |
| Chest pain                                           |                  |                  |  |
| subjects affected / exposed                          | 0 / 41 (0.00%)   | 3 / 45 (6.67%)   |  |
| occurrences (all)                                    | 0                | 3                |  |
| Chills                                               |                  |                  |  |
| subjects affected / exposed                          | 0 / 41 (0.00%)   | 2 / 45 (4.44%)   |  |
| occurrences (all)                                    | 0                | 2                |  |
| Complication associated with device                  |                  |                  |  |
| subjects affected / exposed                          | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                                    | 0                | 0                |  |
| Device related thrombosis                            |                  |                  |  |
| subjects affected / exposed                          | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                                    | 0                | 0                |  |
| Gait disturbance                                     |                  |                  |  |
| subjects affected / exposed                          | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                                    | 0                | 0                |  |
| Fatigue                                              |                  |                  |  |
| subjects affected / exposed                          | 18 / 41 (43.90%) | 13 / 45 (28.89%) |  |
| occurrences (all)                                    | 21               | 17               |  |
| Hernia pain                                          |                  |                  |  |

|                              |                 |                  |
|------------------------------|-----------------|------------------|
| subjects affected / exposed  | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |
| occurrences (all)            | 0               | 0                |
| Injection site extravasation |                 |                  |
| subjects affected / exposed  | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |
| occurrences (all)            | 0               | 0                |
| Influenza like illness       |                 |                  |
| subjects affected / exposed  | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |
| occurrences (all)            | 0               | 0                |
| Localised oedema             |                 |                  |
| subjects affected / exposed  | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |
| occurrences (all)            | 0               | 0                |
| Mucosal inflammation         |                 |                  |
| subjects affected / exposed  | 2 / 41 (4.88%)  | 3 / 45 (6.67%)   |
| occurrences (all)            | 2               | 3                |
| Malaise                      |                 |                  |
| subjects affected / exposed  | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |
| occurrences (all)            | 0               | 0                |
| Non-cardiac chest pain       |                 |                  |
| subjects affected / exposed  | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |
| occurrences (all)            | 0               | 0                |
| Oedema peripheral            |                 |                  |
| subjects affected / exposed  | 9 / 41 (21.95%) | 3 / 45 (6.67%)   |
| occurrences (all)            | 9               | 3                |
| Pain                         |                 |                  |
| subjects affected / exposed  | 3 / 41 (7.32%)  | 2 / 45 (4.44%)   |
| occurrences (all)            | 3               | 2                |
| Performance status decreased |                 |                  |
| subjects affected / exposed  | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |
| occurrences (all)            | 0               | 0                |
| Peripheral swelling          |                 |                  |
| subjects affected / exposed  | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |
| occurrences (all)            | 0               | 0                |
| Pyrexia                      |                 |                  |
| subjects affected / exposed  | 3 / 41 (7.32%)  | 14 / 45 (31.11%) |
| occurrences (all)            | 3               | 19               |
| Swelling face                |                 |                  |

|                                                                                                                          |                        |                        |  |
|--------------------------------------------------------------------------------------------------------------------------|------------------------|------------------------|--|
| subjects affected / exposed<br>occurrences (all)                                                                         | 0 / 41 (0.00%)<br>0    | 0 / 45 (0.00%)<br>0    |  |
| Xerosis<br>subjects affected / exposed<br>occurrences (all)                                                              | 9 / 41 (21.95%)<br>9   | 3 / 45 (6.67%)<br>3    |  |
| Temperature intolerance<br>subjects affected / exposed<br>occurrences (all)                                              | 0 / 41 (0.00%)<br>0    | 0 / 45 (0.00%)<br>0    |  |
| Immune system disorders<br>Seasonal allergy<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 41 (0.00%)<br>0    | 0 / 45 (0.00%)<br>0    |  |
| Reproductive system and breast disorders<br>Heavy menstrual bleeding<br>subjects affected / exposed<br>occurrences (all) | 0 / 41 (0.00%)<br>0    | 0 / 45 (0.00%)<br>0    |  |
| Breast pain<br>subjects affected / exposed<br>occurrences (all)                                                          | 0 / 41 (0.00%)<br>0    | 1 / 45 (2.22%)<br>1    |  |
| Vulvovaginal pruritus<br>subjects affected / exposed<br>occurrences (all)                                                | 0 / 41 (0.00%)<br>0    | 0 / 45 (0.00%)<br>0    |  |
| Respiratory, thoracic and mediastinal disorders<br>Apnoea<br>subjects affected / exposed<br>occurrences (all)            | 0 / 41 (0.00%)<br>0    | 0 / 45 (0.00%)<br>0    |  |
| Cough<br>subjects affected / exposed<br>occurrences (all)                                                                | 11 / 41 (26.83%)<br>12 | 13 / 45 (28.89%)<br>14 |  |
| Dysphonia<br>subjects affected / exposed<br>occurrences (all)                                                            | 0 / 41 (0.00%)<br>0    | 1 / 45 (2.22%)<br>1    |  |
| Dyspnoea<br>subjects affected / exposed<br>occurrences (all)                                                             | 1 / 41 (2.44%)<br>1    | 8 / 45 (17.78%)<br>9   |  |
| Nasal congestion                                                                                                         |                        |                        |  |

|                             |                |                |  |
|-----------------------------|----------------|----------------|--|
| subjects affected / exposed | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 1              | 0              |  |
| Hypoxia                     |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 0              | 0              |  |
| Haemoptysis                 |                |                |  |
| subjects affected / exposed | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 1              | 0              |  |
| Oropharyngeal pain          |                |                |  |
| subjects affected / exposed | 2 / 41 (4.88%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 2              | 0              |  |
| Pleural effusion            |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 4 / 45 (8.89%) |  |
| occurrences (all)           | 0              | 4              |  |
| Pneumonitis                 |                |                |  |
| subjects affected / exposed | 2 / 41 (4.88%) | 3 / 45 (6.67%) |  |
| occurrences (all)           | 4              | 4              |  |
| Pneumothorax                |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 0              | 0              |  |
| Pulmonary embolism          |                |                |  |
| subjects affected / exposed | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 1              | 0              |  |
| Rhinitis allergic           |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 0              | 0              |  |
| Rhinorrhoea                 |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 0              | 0              |  |
| Upper-airway cough syndrome |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 0              | 0              |  |
| Wheezing                    |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 0              | 0              |  |
| Psychiatric disorders       |                |                |  |

|                                         |                  |                  |  |
|-----------------------------------------|------------------|------------------|--|
| Adjustment disorder with depressed mood |                  |                  |  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                       | 0                | 0                |  |
| Affective disorder                      |                  |                  |  |
| subjects affected / exposed             | 3 / 41 (7.32%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                       | 3                | 0                |  |
| Anxiety                                 |                  |                  |  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 1 / 45 (2.22%)   |  |
| occurrences (all)                       | 0                | 1                |  |
| Depression                              |                  |                  |  |
| subjects affected / exposed             | 2 / 41 (4.88%)   | 1 / 45 (2.22%)   |  |
| occurrences (all)                       | 2                | 1                |  |
| Disorientation                          |                  |                  |  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                       | 0                | 0                |  |
| Insomnia                                |                  |                  |  |
| subjects affected / exposed             | 5 / 41 (12.20%)  | 3 / 45 (6.67%)   |  |
| occurrences (all)                       | 5                | 4                |  |
| Libido decreased                        |                  |                  |  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                       | 0                | 0                |  |
| Mental status changes                   |                  |                  |  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                       | 0                | 0                |  |
| Panic attack                            |                  |                  |  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                       | 0                | 0                |  |
| Investigations                          |                  |                  |  |
| Ammonia increased                       |                  |                  |  |
| subjects affected / exposed             | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                       | 0                | 0                |  |
| Alanine aminotransferase increased      |                  |                  |  |
| subjects affected / exposed             | 10 / 41 (24.39%) | 16 / 45 (35.56%) |  |
| occurrences (all)                       | 13               | 25               |  |
| Amylase increased                       |                  |                  |  |

|                                        |                 |                  |
|----------------------------------------|-----------------|------------------|
| subjects affected / exposed            | 1 / 41 (2.44%)  | 10 / 45 (22.22%) |
| occurrences (all)                      | 1               | 10               |
| Blood albumin decreased                |                 |                  |
| subjects affected / exposed            | 4 / 41 (9.76%)  | 7 / 45 (15.56%)  |
| occurrences (all)                      | 8               | 9                |
| Aspartate aminotransferase increased   |                 |                  |
| subjects affected / exposed            | 8 / 41 (19.51%) | 17 / 45 (37.78%) |
| occurrences (all)                      | 12              | 28               |
| Blood bilirubin increased              |                 |                  |
| subjects affected / exposed            | 3 / 41 (7.32%)  | 4 / 45 (8.89%)   |
| occurrences (all)                      | 3               | 4                |
| Blood alkaline phosphatase increased   |                 |                  |
| subjects affected / exposed            | 1 / 41 (2.44%)  | 2 / 45 (4.44%)   |
| occurrences (all)                      | 1               | 2                |
| Blood calcium decreased                |                 |                  |
| subjects affected / exposed            | 4 / 41 (9.76%)  | 1 / 45 (2.22%)   |
| occurrences (all)                      | 13              | 1                |
| Blood calcium increased                |                 |                  |
| subjects affected / exposed            | 0 / 41 (0.00%)  | 1 / 45 (2.22%)   |
| occurrences (all)                      | 0               | 1                |
| Blood cholesterol increased            |                 |                  |
| subjects affected / exposed            | 2 / 41 (4.88%)  | 6 / 45 (13.33%)  |
| occurrences (all)                      | 2               | 7                |
| Blood creatine phosphokinase increased |                 |                  |
| subjects affected / exposed            | 2 / 41 (4.88%)  | 5 / 45 (11.11%)  |
| occurrences (all)                      | 3               | 7                |
| Blood creatinine increased             |                 |                  |
| subjects affected / exposed            | 4 / 41 (9.76%)  | 1 / 45 (2.22%)   |
| occurrences (all)                      | 5               | 1                |
| Blood glucose decreased                |                 |                  |
| subjects affected / exposed            | 0 / 41 (0.00%)  | 1 / 45 (2.22%)   |
| occurrences (all)                      | 0               | 1                |
| Blood lactic acid increased            |                 |                  |

|                                             |                 |                  |
|---------------------------------------------|-----------------|------------------|
| subjects affected / exposed                 | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |
| occurrences (all)                           | 0               | 0                |
| Blood glucose increased                     |                 |                  |
| subjects affected / exposed                 | 3 / 41 (7.32%)  | 5 / 45 (11.11%)  |
| occurrences (all)                           | 3               | 10               |
| Blood magnesium decreased                   |                 |                  |
| subjects affected / exposed                 | 2 / 41 (4.88%)  | 10 / 45 (22.22%) |
| occurrences (all)                           | 2               | 12               |
| Blood phosphorus increased                  |                 |                  |
| subjects affected / exposed                 | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |
| occurrences (all)                           | 0               | 0                |
| Blood potassium decreased                   |                 |                  |
| subjects affected / exposed                 | 3 / 41 (7.32%)  | 1 / 45 (2.22%)   |
| occurrences (all)                           | 3               | 1                |
| Blood prolactin increased                   |                 |                  |
| subjects affected / exposed                 | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |
| occurrences (all)                           | 0               | 0                |
| Blood sodium decreased                      |                 |                  |
| subjects affected / exposed                 | 7 / 41 (17.07%) | 5 / 45 (11.11%)  |
| occurrences (all)                           | 11              | 6                |
| Blood thyroid stimulating hormone decreased |                 |                  |
| subjects affected / exposed                 | 1 / 41 (2.44%)  | 2 / 45 (4.44%)   |
| occurrences (all)                           | 1               | 2                |
| Blood thyroid stimulating hormone increased |                 |                  |
| subjects affected / exposed                 | 2 / 41 (4.88%)  | 6 / 45 (13.33%)  |
| occurrences (all)                           | 2               | 6                |
| Blood uric acid increased                   |                 |                  |
| subjects affected / exposed                 | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |
| occurrences (all)                           | 0               | 0                |
| C-reactive protein increased                |                 |                  |
| subjects affected / exposed                 | 0 / 41 (0.00%)  | 1 / 45 (2.22%)   |
| occurrences (all)                           | 0               | 1                |
| Cardiac murmur                              |                 |                  |

|                                          |                 |                 |  |
|------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed              | 0 / 41 (0.00%)  | 0 / 45 (0.00%)  |  |
| occurrences (all)                        | 0               | 0               |  |
| Gamma-glutamyltransferase increased      |                 |                 |  |
| subjects affected / exposed              | 1 / 41 (2.44%)  | 6 / 45 (13.33%) |  |
| occurrences (all)                        | 1               | 6               |  |
| Haemoglobin decreased                    |                 |                 |  |
| subjects affected / exposed              | 0 / 41 (0.00%)  | 1 / 45 (2.22%)  |  |
| occurrences (all)                        | 0               | 1               |  |
| International normalised ratio increased |                 |                 |  |
| subjects affected / exposed              | 0 / 41 (0.00%)  | 0 / 45 (0.00%)  |  |
| occurrences (all)                        | 0               | 0               |  |
| Lipase increased                         |                 |                 |  |
| subjects affected / exposed              | 5 / 41 (12.20%) | 8 / 45 (17.78%) |  |
| occurrences (all)                        | 6               | 9               |  |
| Liver function test increased            |                 |                 |  |
| subjects affected / exposed              | 0 / 41 (0.00%)  | 0 / 45 (0.00%)  |  |
| occurrences (all)                        | 0               | 0               |  |
| Neutrophil count decreased               |                 |                 |  |
| subjects affected / exposed              | 1 / 41 (2.44%)  | 3 / 45 (6.67%)  |  |
| occurrences (all)                        | 1               | 6               |  |
| Platelet count decreased                 |                 |                 |  |
| subjects affected / exposed              | 2 / 41 (4.88%)  | 5 / 45 (11.11%) |  |
| occurrences (all)                        | 2               | 6               |  |
| Troponin I increased                     |                 |                 |  |
| subjects affected / exposed              | 1 / 41 (2.44%)  | 0 / 45 (0.00%)  |  |
| occurrences (all)                        | 1               | 0               |  |
| Transaminases increased                  |                 |                 |  |
| subjects affected / exposed              | 0 / 41 (0.00%)  | 0 / 45 (0.00%)  |  |
| occurrences (all)                        | 0               | 0               |  |
| Troponin increased                       |                 |                 |  |
| subjects affected / exposed              | 4 / 41 (9.76%)  | 2 / 45 (4.44%)  |  |
| occurrences (all)                        | 5               | 2               |  |
| Urine phosphorus increased               |                 |                 |  |

|                                                |                  |                 |  |
|------------------------------------------------|------------------|-----------------|--|
| subjects affected / exposed                    | 0 / 41 (0.00%)   | 0 / 45 (0.00%)  |  |
| occurrences (all)                              | 0                | 0               |  |
| Urine calcium increased                        |                  |                 |  |
| subjects affected / exposed                    | 0 / 41 (0.00%)   | 0 / 45 (0.00%)  |  |
| occurrences (all)                              | 0                | 0               |  |
| Weight decreased                               |                  |                 |  |
| subjects affected / exposed                    | 13 / 41 (31.71%) | 5 / 45 (11.11%) |  |
| occurrences (all)                              | 14               | 5               |  |
| White blood cell count decreased               |                  |                 |  |
| subjects affected / exposed                    | 0 / 41 (0.00%)   | 0 / 45 (0.00%)  |  |
| occurrences (all)                              | 0                | 0               |  |
| White blood cell count increased               |                  |                 |  |
| subjects affected / exposed                    | 0 / 41 (0.00%)   | 0 / 45 (0.00%)  |  |
| occurrences (all)                              | 0                | 0               |  |
| Injury, poisoning and procedural complications |                  |                 |  |
| Fall                                           |                  |                 |  |
| subjects affected / exposed                    | 0 / 41 (0.00%)   | 0 / 45 (0.00%)  |  |
| occurrences (all)                              | 0                | 0               |  |
| Femur fracture                                 |                  |                 |  |
| subjects affected / exposed                    | 0 / 41 (0.00%)   | 0 / 45 (0.00%)  |  |
| occurrences (all)                              | 0                | 0               |  |
| Infusion related reaction                      |                  |                 |  |
| subjects affected / exposed                    | 0 / 41 (0.00%)   | 0 / 45 (0.00%)  |  |
| occurrences (all)                              | 0                | 0               |  |
| Muscle strain                                  |                  |                 |  |
| subjects affected / exposed                    | 0 / 41 (0.00%)   | 0 / 45 (0.00%)  |  |
| occurrences (all)                              | 0                | 0               |  |
| Lip injury                                     |                  |                 |  |
| subjects affected / exposed                    | 0 / 41 (0.00%)   | 0 / 45 (0.00%)  |  |
| occurrences (all)                              | 0                | 0               |  |
| Procedural pain                                |                  |                 |  |
| subjects affected / exposed                    | 0 / 41 (0.00%)   | 1 / 45 (2.22%)  |  |
| occurrences (all)                              | 0                | 1               |  |
| Rib fracture                                   |                  |                 |  |

|                               |                |                |  |
|-------------------------------|----------------|----------------|--|
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)             | 0              | 0              |  |
| Skin abrasion                 |                |                |  |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)             | 0              | 0              |  |
| Tooth fracture                |                |                |  |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)             | 0              | 0              |  |
| Vascular access site erythema |                |                |  |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)             | 0              | 0              |  |
| Wound secretion               |                |                |  |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)             | 0              | 0              |  |
| Cardiac disorders             |                |                |  |
| Atrial fibrillation           |                |                |  |
| subjects affected / exposed   | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences (all)             | 1              | 0              |  |
| Palpitations                  |                |                |  |
| subjects affected / exposed   | 2 / 41 (4.88%) | 0 / 45 (0.00%) |  |
| occurrences (all)             | 2              | 0              |  |
| Pericardial effusion          |                |                |  |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)             | 0              | 0              |  |
| Sinus bradycardia             |                |                |  |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)             | 0              | 0              |  |
| Sinus tachycardia             |                |                |  |
| subjects affected / exposed   | 3 / 41 (7.32%) | 3 / 45 (6.67%) |  |
| occurrences (all)             | 4              | 3              |  |
| Tachycardia                   |                |                |  |
| subjects affected / exposed   | 1 / 41 (2.44%) | 2 / 45 (4.44%) |  |
| occurrences (all)             | 1              | 2              |  |
| Nervous system disorders      |                |                |  |
| Aphasia                       |                |                |  |

|                               |                |                 |
|-------------------------------|----------------|-----------------|
| subjects affected / exposed   | 1 / 41 (2.44%) | 0 / 45 (0.00%)  |
| occurrences (all)             | 1              | 0               |
| Cognitive disorder            |                |                 |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%)  |
| occurrences (all)             | 0              | 0               |
| Dysarthria                    |                |                 |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%)  |
| occurrences (all)             | 0              | 0               |
| Dizziness                     |                |                 |
| subjects affected / exposed   | 1 / 41 (2.44%) | 2 / 45 (4.44%)  |
| occurrences (all)             | 1              | 3               |
| Headache                      |                |                 |
| subjects affected / exposed   | 1 / 41 (2.44%) | 9 / 45 (20.00%) |
| occurrences (all)             | 1              | 10              |
| Dysgeusia                     |                |                 |
| subjects affected / exposed   | 2 / 41 (4.88%) | 1 / 45 (2.22%)  |
| occurrences (all)             | 2              | 1               |
| Hyperaesthesia                |                |                 |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%)  |
| occurrences (all)             | 0              | 0               |
| Lethargy                      |                |                 |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%)  |
| occurrences (all)             | 0              | 0               |
| Neuralgia                     |                |                 |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%)  |
| occurrences (all)             | 0              | 0               |
| Neuropathy peripheral         |                |                 |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%)  |
| occurrences (all)             | 0              | 0               |
| Paraesthesia                  |                |                 |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%)  |
| occurrences (all)             | 0              | 0               |
| Parkinson's disease           |                |                 |
| subjects affected / exposed   | 0 / 41 (0.00%) | 0 / 45 (0.00%)  |
| occurrences (all)             | 0              | 0               |
| Peripheral sensory neuropathy |                |                 |

|                                      |                  |                  |  |
|--------------------------------------|------------------|------------------|--|
| subjects affected / exposed          | 0 / 41 (0.00%)   | 1 / 45 (2.22%)   |  |
| occurrences (all)                    | 0                | 1                |  |
| Peripheral motor neuropathy          |                  |                  |  |
| subjects affected / exposed          | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                    | 0                | 0                |  |
| Post herpetic neuralgia              |                  |                  |  |
| subjects affected / exposed          | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                    | 0                | 0                |  |
| Restless legs syndrome               |                  |                  |  |
| subjects affected / exposed          | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                    | 0                | 0                |  |
| Radiculopathy                        |                  |                  |  |
| subjects affected / exposed          | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                    | 0                | 0                |  |
| Somnolence                           |                  |                  |  |
| subjects affected / exposed          | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                    | 0                | 0                |  |
| Sciatica                             |                  |                  |  |
| subjects affected / exposed          | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                    | 0                | 0                |  |
| Tension headache                     |                  |                  |  |
| subjects affected / exposed          | 0 / 41 (0.00%)   | 1 / 45 (2.22%)   |  |
| occurrences (all)                    | 0                | 1                |  |
| Tremor                               |                  |                  |  |
| subjects affected / exposed          | 0 / 41 (0.00%)   | 2 / 45 (4.44%)   |  |
| occurrences (all)                    | 0                | 2                |  |
| Blood and lymphatic system disorders |                  |                  |  |
| Anaemia                              |                  |                  |  |
| subjects affected / exposed          | 21 / 41 (51.22%) | 23 / 45 (51.11%) |  |
| occurrences (all)                    | 35               | 32               |  |
| Eosinophilia                         |                  |                  |  |
| subjects affected / exposed          | 1 / 41 (2.44%)   | 2 / 45 (4.44%)   |  |
| occurrences (all)                    | 2                | 2                |  |
| Iron deficiency anaemia              |                  |                  |  |
| subjects affected / exposed          | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                    | 0                | 0                |  |

|                             |                |                |  |
|-----------------------------|----------------|----------------|--|
| Leukocytosis                |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 0              | 0              |  |
| Lymphopenia                 |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences (all)           | 0              | 1              |  |
| Thrombocytopenia            |                |                |  |
| subjects affected / exposed | 4 / 41 (9.76%) | 3 / 45 (6.67%) |  |
| occurrences (all)           | 4              | 3              |  |
| Neutropenia                 |                |                |  |
| subjects affected / exposed | 2 / 41 (4.88%) | 1 / 45 (2.22%) |  |
| occurrences (all)           | 2              | 2              |  |
| Ear and labyrinth disorders |                |                |  |
| Ear pain                    |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 0              | 0              |  |
| Hypoacusis                  |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 0              | 0              |  |
| Vertigo                     |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 2 / 45 (4.44%) |  |
| occurrences (all)           | 0              | 2              |  |
| Eye disorders               |                |                |  |
| Dry eye                     |                |                |  |
| subjects affected / exposed | 1 / 41 (2.44%) | 1 / 45 (2.22%) |  |
| occurrences (all)           | 1              | 1              |  |
| Iridocyclitis               |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 0              | 0              |  |
| Eyelid irritation           |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 0              | 0              |  |
| Vision blurred              |                |                |  |
| subjects affected / exposed | 0 / 41 (0.00%) | 1 / 45 (2.22%) |  |
| occurrences (all)           | 0              | 1              |  |
| Swelling of eyelid          |                |                |  |

|                             |                  |                  |  |
|-----------------------------|------------------|------------------|--|
| subjects affected / exposed | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)           | 0                | 0                |  |
| Gastrointestinal disorders  |                  |                  |  |
| Abdominal discomfort        |                  |                  |  |
| subjects affected / exposed | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)           | 0                | 0                |  |
| Abdominal distension        |                  |                  |  |
| subjects affected / exposed | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)           | 0                | 0                |  |
| Abdominal pain              |                  |                  |  |
| subjects affected / exposed | 3 / 41 (7.32%)   | 8 / 45 (17.78%)  |  |
| occurrences (all)           | 3                | 8                |  |
| Abdominal pain lower        |                  |                  |  |
| subjects affected / exposed | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)           | 0                | 0                |  |
| Abdominal pain upper        |                  |                  |  |
| subjects affected / exposed | 0 / 41 (0.00%)   | 3 / 45 (6.67%)   |  |
| occurrences (all)           | 0                | 5                |  |
| Ascites                     |                  |                  |  |
| subjects affected / exposed | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)           | 0                | 0                |  |
| Colitis                     |                  |                  |  |
| subjects affected / exposed | 2 / 41 (4.88%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)           | 2                | 0                |  |
| Constipation                |                  |                  |  |
| subjects affected / exposed | 6 / 41 (14.63%)  | 4 / 45 (8.89%)   |  |
| occurrences (all)           | 8                | 4                |  |
| Diarrhoea                   |                  |                  |  |
| subjects affected / exposed | 19 / 41 (46.34%) | 19 / 45 (42.22%) |  |
| occurrences (all)           | 28               | 26               |  |
| Dyspepsia                   |                  |                  |  |
| subjects affected / exposed | 0 / 41 (0.00%)   | 2 / 45 (4.44%)   |  |
| occurrences (all)           | 0                | 3                |  |
| Dry mouth                   |                  |                  |  |
| subjects affected / exposed | 3 / 41 (7.32%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)           | 3                | 0                |  |

|                                    |                  |                  |
|------------------------------------|------------------|------------------|
| Dysphagia                          |                  |                  |
| subjects affected / exposed        | 2 / 41 (4.88%)   | 1 / 45 (2.22%)   |
| occurrences (all)                  | 2                | 1                |
| Enteritis                          |                  |                  |
| subjects affected / exposed        | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |
| occurrences (all)                  | 0                | 0                |
| Flatulence                         |                  |                  |
| subjects affected / exposed        | 1 / 41 (2.44%)   | 2 / 45 (4.44%)   |
| occurrences (all)                  | 2                | 2                |
| Frequent bowel movements           |                  |                  |
| subjects affected / exposed        | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |
| occurrences (all)                  | 0                | 0                |
| Gastritis                          |                  |                  |
| subjects affected / exposed        | 1 / 41 (2.44%)   | 1 / 45 (2.22%)   |
| occurrences (all)                  | 1                | 1                |
| Gastrointestinal motility disorder |                  |                  |
| subjects affected / exposed        | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |
| occurrences (all)                  | 0                | 0                |
| Gastrointestinal haemorrhage       |                  |                  |
| subjects affected / exposed        | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |
| occurrences (all)                  | 0                | 0                |
| Gastrooesophageal reflux disease   |                  |                  |
| subjects affected / exposed        | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |
| occurrences (all)                  | 0                | 0                |
| Immune-mediated enterocolitis      |                  |                  |
| subjects affected / exposed        | 2 / 41 (4.88%)   | 0 / 45 (0.00%)   |
| occurrences (all)                  | 2                | 0                |
| Impaired gastric emptying          |                  |                  |
| subjects affected / exposed        | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |
| occurrences (all)                  | 0                | 0                |
| Mouth ulceration                   |                  |                  |
| subjects affected / exposed        | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |
| occurrences (all)                  | 0                | 0                |
| Nausea                             |                  |                  |
| subjects affected / exposed        | 12 / 41 (29.27%) | 13 / 45 (28.89%) |
| occurrences (all)                  | 13               | 16               |

|                                                                                     |                     |                        |  |
|-------------------------------------------------------------------------------------|---------------------|------------------------|--|
| Oesophageal varices haemorrhage<br>subjects affected / exposed<br>occurrences (all) | 0 / 41 (0.00%)<br>0 | 0 / 45 (0.00%)<br>0    |  |
| Oral dysaesthesia<br>subjects affected / exposed<br>occurrences (all)               | 0 / 41 (0.00%)<br>0 | 0 / 45 (0.00%)<br>0    |  |
| Proctalgia<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 41 (0.00%)<br>0 | 0 / 45 (0.00%)<br>0    |  |
| Rectal haemorrhage<br>subjects affected / exposed<br>occurrences (all)              | 0 / 41 (0.00%)<br>0 | 0 / 45 (0.00%)<br>0    |  |
| Stomatitis<br>subjects affected / exposed<br>occurrences (all)                      | 2 / 41 (4.88%)<br>2 | 3 / 45 (6.67%)<br>5    |  |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)                        | 3 / 41 (7.32%)<br>5 | 11 / 45 (24.44%)<br>13 |  |
| Hepatobiliary disorders                                                             |                     |                        |  |
| Biliary obstruction<br>subjects affected / exposed<br>occurrences (all)             | 0 / 41 (0.00%)<br>0 | 0 / 45 (0.00%)<br>0    |  |
| Autoimmune hepatitis<br>subjects affected / exposed<br>occurrences (all)            | 0 / 41 (0.00%)<br>0 | 0 / 45 (0.00%)<br>0    |  |
| Hepatitis<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 41 (0.00%)<br>0 | 1 / 45 (2.22%)<br>1    |  |
| Hepatic failure<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 41 (0.00%)<br>0 | 0 / 45 (0.00%)<br>0    |  |
| Hyperbilirubinaemia<br>subjects affected / exposed<br>occurrences (all)             | 0 / 41 (0.00%)<br>0 | 0 / 45 (0.00%)<br>0    |  |
| Hypertransaminasaemia                                                               |                     |                        |  |

|                                        |                |                |  |
|----------------------------------------|----------------|----------------|--|
| subjects affected / exposed            | 1 / 41 (2.44%) | 2 / 45 (4.44%) |  |
| occurrences (all)                      | 1              | 2              |  |
| Immune-mediated hepatitis              |                |                |  |
| subjects affected / exposed            | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences (all)                      | 1              | 0              |  |
| Jaundice cholestatic                   |                |                |  |
| subjects affected / exposed            | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)                      | 0              | 0              |  |
| Portal hypertension                    |                |                |  |
| subjects affected / exposed            | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)                      | 0              | 0              |  |
| Skin and subcutaneous tissue disorders |                |                |  |
| Alopecia                               |                |                |  |
| subjects affected / exposed            | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)                      | 0              | 0              |  |
| Acquired porokeratosis                 |                |                |  |
| subjects affected / exposed            | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)                      | 0              | 0              |  |
| Dermatitis acneiform                   |                |                |  |
| subjects affected / exposed            | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)                      | 0              | 0              |  |
| Drug eruption                          |                |                |  |
| subjects affected / exposed            | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)                      | 0              | 0              |  |
| Dry skin                               |                |                |  |
| subjects affected / exposed            | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)                      | 0              | 0              |  |
| Eczema                                 |                |                |  |
| subjects affected / exposed            | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)                      | 0              | 0              |  |
| Erythema                               |                |                |  |
| subjects affected / exposed            | 1 / 41 (2.44%) | 0 / 45 (0.00%) |  |
| occurrences (all)                      | 1              | 0              |  |
| Ecchymosis                             |                |                |  |
| subjects affected / exposed            | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)                      | 0              | 0              |  |

|                                            |                  |                  |  |
|--------------------------------------------|------------------|------------------|--|
| Night sweats                               |                  |                  |  |
| subjects affected / exposed                | 0 / 41 (0.00%)   | 1 / 45 (2.22%)   |  |
| occurrences (all)                          | 0                | 1                |  |
| Keloid scar                                |                  |                  |  |
| subjects affected / exposed                | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                          | 0                | 0                |  |
| Leukoplakia                                |                  |                  |  |
| subjects affected / exposed                | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                          | 0                | 0                |  |
| Rash                                       |                  |                  |  |
| subjects affected / exposed                | 6 / 41 (14.63%)  | 7 / 45 (15.56%)  |  |
| occurrences (all)                          | 7                | 8                |  |
| Pruritus                                   |                  |                  |  |
| subjects affected / exposed                | 16 / 41 (39.02%) | 12 / 45 (26.67%) |  |
| occurrences (all)                          | 17               | 16               |  |
| Palmar-plantar erythrodysesthesia syndrome |                  |                  |  |
| subjects affected / exposed                | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                          | 0                | 0                |  |
| Rash maculo-papular                        |                  |                  |  |
| subjects affected / exposed                | 3 / 41 (7.32%)   | 4 / 45 (8.89%)   |  |
| occurrences (all)                          | 3                | 4                |  |
| Rash macular                               |                  |                  |  |
| subjects affected / exposed                | 1 / 41 (2.44%)   | 1 / 45 (2.22%)   |  |
| occurrences (all)                          | 2                | 1                |  |
| Rash erythematous                          |                  |                  |  |
| subjects affected / exposed                | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                          | 0                | 0                |  |
| Rash pruritic                              |                  |                  |  |
| subjects affected / exposed                | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                          | 0                | 0                |  |
| Rash vesicular                             |                  |                  |  |
| subjects affected / exposed                | 0 / 41 (0.00%)   | 0 / 45 (0.00%)   |  |
| occurrences (all)                          | 0                | 0                |  |
| Transient acantholytic dermatosis          |                  |                  |  |

|                                                                                                        |                      |                     |  |
|--------------------------------------------------------------------------------------------------------|----------------------|---------------------|--|
| subjects affected / exposed<br>occurrences (all)                                                       | 0 / 41 (0.00%)<br>0  | 0 / 45 (0.00%)<br>0 |  |
| Skin hypopigmentation<br>subjects affected / exposed<br>occurrences (all)                              | 0 / 41 (0.00%)<br>0  | 0 / 45 (0.00%)<br>0 |  |
| Urticaria<br>subjects affected / exposed<br>occurrences (all)                                          | 1 / 41 (2.44%)<br>1  | 0 / 45 (0.00%)<br>0 |  |
| Vitiligo<br>subjects affected / exposed<br>occurrences (all)                                           | 0 / 41 (0.00%)<br>0  | 0 / 45 (0.00%)<br>0 |  |
| Renal and urinary disorders<br>Acute kidney injury<br>subjects affected / exposed<br>occurrences (all) | 0 / 41 (0.00%)<br>0  | 0 / 45 (0.00%)<br>0 |  |
| Pollakiuria<br>subjects affected / exposed<br>occurrences (all)                                        | 0 / 41 (0.00%)<br>0  | 0 / 45 (0.00%)<br>0 |  |
| Proteinuria<br>subjects affected / exposed<br>occurrences (all)                                        | 0 / 41 (0.00%)<br>0  | 1 / 45 (2.22%)<br>1 |  |
| Haematuria<br>subjects affected / exposed<br>occurrences (all)                                         | 2 / 41 (4.88%)<br>2  | 0 / 45 (0.00%)<br>0 |  |
| Tubulointerstitial nephritis<br>subjects affected / exposed<br>occurrences (all)                       | 1 / 41 (2.44%)<br>1  | 0 / 45 (0.00%)<br>0 |  |
| Endocrine disorders<br>Adrenal insufficiency<br>subjects affected / exposed<br>occurrences (all)       | 5 / 41 (12.20%)<br>5 | 2 / 45 (4.44%)<br>2 |  |
| Autoimmune thyroiditis<br>subjects affected / exposed<br>occurrences (all)                             | 0 / 41 (0.00%)<br>0  | 0 / 45 (0.00%)<br>0 |  |
| Hyperthyroidism                                                                                        |                      |                     |  |

|                                                 |                 |                  |  |
|-------------------------------------------------|-----------------|------------------|--|
| subjects affected / exposed                     | 5 / 41 (12.20%) | 4 / 45 (8.89%)   |  |
| occurrences (all)                               | 5               | 4                |  |
| Hypophysitis                                    |                 |                  |  |
| subjects affected / exposed                     | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |  |
| occurrences (all)                               | 0               | 0                |  |
| Hypopituitarism                                 |                 |                  |  |
| subjects affected / exposed                     | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |  |
| occurrences (all)                               | 0               | 0                |  |
| Hypothyroidism                                  |                 |                  |  |
| subjects affected / exposed                     | 4 / 41 (9.76%)  | 8 / 45 (17.78%)  |  |
| occurrences (all)                               | 4               | 8                |  |
| Thyroiditis                                     |                 |                  |  |
| subjects affected / exposed                     | 1 / 41 (2.44%)  | 0 / 45 (0.00%)   |  |
| occurrences (all)                               | 1               | 0                |  |
| Inappropriate antidiuretic hormone secretion    |                 |                  |  |
| subjects affected / exposed                     | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |  |
| occurrences (all)                               | 0               | 0                |  |
| Musculoskeletal and connective tissue disorders |                 |                  |  |
| Arthralgia                                      |                 |                  |  |
| subjects affected / exposed                     | 6 / 41 (14.63%) | 12 / 45 (26.67%) |  |
| occurrences (all)                               | 7               | 12               |  |
| Back pain                                       |                 |                  |  |
| subjects affected / exposed                     | 4 / 41 (9.76%)  | 2 / 45 (4.44%)   |  |
| occurrences (all)                               | 5               | 2                |  |
| Groin pain                                      |                 |                  |  |
| subjects affected / exposed                     | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |  |
| occurrences (all)                               | 0               | 0                |  |
| Hypercreatinaemia                               |                 |                  |  |
| subjects affected / exposed                     | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |  |
| occurrences (all)                               | 0               | 0                |  |
| Joint swelling                                  |                 |                  |  |
| subjects affected / exposed                     | 0 / 41 (0.00%)  | 0 / 45 (0.00%)   |  |
| occurrences (all)                               | 0               | 0                |  |
| Muscular weakness                               |                 |                  |  |

|                             |                 |                 |  |
|-----------------------------|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 41 (0.00%)  | 1 / 45 (2.22%)  |  |
| occurrences (all)           | 0               | 1               |  |
| Muscle spasms               |                 |                 |  |
| subjects affected / exposed | 3 / 41 (7.32%)  | 3 / 45 (6.67%)  |  |
| occurrences (all)           | 3               | 3               |  |
| Musculoskeletal chest pain  |                 |                 |  |
| subjects affected / exposed | 0 / 41 (0.00%)  | 2 / 45 (4.44%)  |  |
| occurrences (all)           | 0               | 2               |  |
| Myalgia                     |                 |                 |  |
| subjects affected / exposed | 5 / 41 (12.20%) | 6 / 45 (13.33%) |  |
| occurrences (all)           | 5               | 8               |  |
| Myositis                    |                 |                 |  |
| subjects affected / exposed | 0 / 41 (0.00%)  | 1 / 45 (2.22%)  |  |
| occurrences (all)           | 0               | 1               |  |
| Neck pain                   |                 |                 |  |
| subjects affected / exposed | 0 / 41 (0.00%)  | 1 / 45 (2.22%)  |  |
| occurrences (all)           | 0               | 1               |  |
| Pain in extremity           |                 |                 |  |
| subjects affected / exposed | 2 / 41 (4.88%)  | 2 / 45 (4.44%)  |  |
| occurrences (all)           | 2               | 2               |  |
| Sacral pain                 |                 |                 |  |
| subjects affected / exposed | 0 / 41 (0.00%)  | 0 / 45 (0.00%)  |  |
| occurrences (all)           | 0               | 0               |  |
| Infections and infestations |                 |                 |  |
| Bronchitis                  |                 |                 |  |
| subjects affected / exposed | 3 / 41 (7.32%)  | 2 / 45 (4.44%)  |  |
| occurrences (all)           | 4               | 2               |  |
| Campylobacter infection     |                 |                 |  |
| subjects affected / exposed | 0 / 41 (0.00%)  | 0 / 45 (0.00%)  |  |
| occurrences (all)           | 0               | 0               |  |
| COVID-19                    |                 |                 |  |
| subjects affected / exposed | 2 / 41 (4.88%)  | 1 / 45 (2.22%)  |  |
| occurrences (all)           | 2               | 1               |  |
| Candida infection           |                 |                 |  |
| subjects affected / exposed | 0 / 41 (0.00%)  | 0 / 45 (0.00%)  |  |
| occurrences (all)           | 0               | 0               |  |

|                             |                |                |
|-----------------------------|----------------|----------------|
| Cellulitis                  |                |                |
| subjects affected / exposed | 0 / 41 (0.00%) | 2 / 45 (4.44%) |
| occurrences (all)           | 0              | 2              |
| Conjunctivitis              |                |                |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |
| occurrences (all)           | 0              | 0              |
| Cystitis                    |                |                |
| subjects affected / exposed | 1 / 41 (2.44%) | 0 / 45 (0.00%) |
| occurrences (all)           | 1              | 0              |
| Diverticulitis              |                |                |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |
| occurrences (all)           | 0              | 0              |
| Eye infection bacterial     |                |                |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |
| occurrences (all)           | 0              | 0              |
| Folliculitis                |                |                |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |
| occurrences (all)           | 0              | 0              |
| Gastroenteritis             |                |                |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |
| occurrences (all)           | 0              | 0              |
| Hepatitis viral             |                |                |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |
| occurrences (all)           | 0              | 0              |
| Gastrointestinal infection  |                |                |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |
| occurrences (all)           | 0              | 0              |
| Herpes zoster               |                |                |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |
| occurrences (all)           | 0              | 0              |
| Hordeolum                   |                |                |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |
| occurrences (all)           | 0              | 0              |
| Influenza                   |                |                |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |
| occurrences (all)           | 0              | 0              |

|                                   |                 |                |
|-----------------------------------|-----------------|----------------|
| Localised infection               |                 |                |
| subjects affected / exposed       | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)                 | 0               | 0              |
| Mucosal infection                 |                 |                |
| subjects affected / exposed       | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)                 | 0               | 0              |
| Nasopharyngitis                   |                 |                |
| subjects affected / exposed       | 2 / 41 (4.88%)  | 0 / 45 (0.00%) |
| occurrences (all)                 | 2               | 0              |
| Oral candidiasis                  |                 |                |
| subjects affected / exposed       | 0 / 41 (0.00%)  | 1 / 45 (2.22%) |
| occurrences (all)                 | 0               | 1              |
| Norovirus infection               |                 |                |
| subjects affected / exposed       | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)                 | 0               | 0              |
| Pharyngitis                       |                 |                |
| subjects affected / exposed       | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)                 | 0               | 0              |
| Rash pustular                     |                 |                |
| subjects affected / exposed       | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)                 | 0               | 0              |
| Pneumonia                         |                 |                |
| subjects affected / exposed       | 5 / 41 (12.20%) | 1 / 45 (2.22%) |
| occurrences (all)                 | 6               | 1              |
| Soft tissue infection             |                 |                |
| subjects affected / exposed       | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)                 | 0               | 0              |
| Skin infection                    |                 |                |
| subjects affected / exposed       | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)                 | 0               | 0              |
| Spontaneous bacterial peritonitis |                 |                |
| subjects affected / exposed       | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)                 | 0               | 0              |
| Upper respiratory tract infection |                 |                |
| subjects affected / exposed       | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)                 | 0               | 0              |

|                                                                                    |                        |                        |  |
|------------------------------------------------------------------------------------|------------------------|------------------------|--|
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)        | 6 / 41 (14.63%)<br>7   | 8 / 45 (17.78%)<br>12  |  |
| Staphylococcal infection<br>subjects affected / exposed<br>occurrences (all)       | 0 / 41 (0.00%)<br>0    | 0 / 45 (0.00%)<br>0    |  |
| Vascular access site infection<br>subjects affected / exposed<br>occurrences (all) | 0 / 41 (0.00%)<br>0    | 0 / 45 (0.00%)<br>0    |  |
| Viral infection<br>subjects affected / exposed<br>occurrences (all)                | 0 / 41 (0.00%)<br>0    | 0 / 45 (0.00%)<br>0    |  |
| Metabolism and nutrition disorders                                                 |                        |                        |  |
| Decreased appetite<br>subjects affected / exposed<br>occurrences (all)             | 16 / 41 (39.02%)<br>16 | 13 / 45 (28.89%)<br>14 |  |
| Dehydration<br>subjects affected / exposed<br>occurrences (all)                    | 1 / 41 (2.44%)<br>1    | 1 / 45 (2.22%)<br>1    |  |
| Electrolyte imbalance<br>subjects affected / exposed<br>occurrences (all)          | 0 / 41 (0.00%)<br>0    | 0 / 45 (0.00%)<br>0    |  |
| Hyperglycaemia<br>subjects affected / exposed<br>occurrences (all)                 | 3 / 41 (7.32%)<br>3    | 5 / 45 (11.11%)<br>9   |  |
| Hypercalcaemia<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 41 (0.00%)<br>0    | 1 / 45 (2.22%)<br>1    |  |
| Hyperkalaemia<br>subjects affected / exposed<br>occurrences (all)                  | 1 / 41 (2.44%)<br>1    | 0 / 45 (0.00%)<br>0    |  |
| Hypermagnesaemia<br>subjects affected / exposed<br>occurrences (all)               | 0 / 41 (0.00%)<br>0    | 0 / 45 (0.00%)<br>0    |  |
| Hyperlipasaemia                                                                    |                        |                        |  |

|                             |                 |                |
|-----------------------------|-----------------|----------------|
| subjects affected / exposed | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)           | 0               | 0              |
| Hyperuricaemia              |                 |                |
| subjects affected / exposed | 1 / 41 (2.44%)  | 0 / 45 (0.00%) |
| occurrences (all)           | 1               | 0              |
| Hypernatraemia              |                 |                |
| subjects affected / exposed | 0 / 41 (0.00%)  | 1 / 45 (2.22%) |
| occurrences (all)           | 0               | 1              |
| Hypoalbuminaemia            |                 |                |
| subjects affected / exposed | 1 / 41 (2.44%)  | 1 / 45 (2.22%) |
| occurrences (all)           | 1               | 2              |
| Hypocalcaemia               |                 |                |
| subjects affected / exposed | 2 / 41 (4.88%)  | 1 / 45 (2.22%) |
| occurrences (all)           | 3               | 1              |
| Hypochloraemia              |                 |                |
| subjects affected / exposed | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)           | 0               | 0              |
| Hypokalaemia                |                 |                |
| subjects affected / exposed | 3 / 41 (7.32%)  | 1 / 45 (2.22%) |
| occurrences (all)           | 5               | 1              |
| Hypomagnesaemia             |                 |                |
| subjects affected / exposed | 2 / 41 (4.88%)  | 3 / 45 (6.67%) |
| occurrences (all)           | 2               | 3              |
| Hyponatraemia               |                 |                |
| subjects affected / exposed | 7 / 41 (17.07%) | 4 / 45 (8.89%) |
| occurrences (all)           | 9               | 5              |
| Hypovolaemia                |                 |                |
| subjects affected / exposed | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)           | 0               | 0              |
| Hypophosphataemia           |                 |                |
| subjects affected / exposed | 1 / 41 (2.44%)  | 0 / 45 (0.00%) |
| occurrences (all)           | 1               | 0              |
| Iron deficiency             |                 |                |
| subjects affected / exposed | 0 / 41 (0.00%)  | 0 / 45 (0.00%) |
| occurrences (all)           | 0               | 0              |
| Malnutrition                |                 |                |

|                             |                |                |  |
|-----------------------------|----------------|----------------|--|
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 45 (0.00%) |  |
| occurrences (all)           | 0              | 0              |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 20 November 2017 | Includes responses to FDA questions about bladder and breast cancer population inclusion criteria, DLT criteria including ocular events, discontinuation from study treatment, clarification of expression of some tumor markers, updated imaging, biopsy and infusion time language.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 24 January 2018  | Expand Part 1B tumor types, clarify the change in frequency of scans up to Week 48 versus thereafter, add co-administration of BMS-986249 + nivolumab in Part 1B, update 2 year treatment duration, add PCWG3 for prostate cancer, and minor typographical updates were made for consistency and clarity of the words participants, patients, and subjects.                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 25 May 2018      | Change dose-limiting toxicity evaluation period, change Parts 1A and 1B treatment assignments, provide a window for clinic visits, incorporate Administrative Letter 01, and minor typographical updates were made for consistency and clarity.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 01 March 2019    | This is a revised protocol to define the Part 2A Expansion Phase, which includes concurrent evaluation of three different dose regimens of BMS-986249 in combination with nivolumab in relation to two standard of care reference arms in a randomized setting in melanoma. This protocol revision also updates DLT criteria, updates inclusion/exclusion criteria, changes the on-treatment biopsy timing, and provides clarifications around planned dose level modifications/intermediate dose levels, and incorporates other clarifying modifications.                                                                                                                                                                                                                    |
| 01 May 2019      | This is a revised protocol to explicitly mention encephalitis as an example of a possible neurological adverse event, updates management algorithms for immuno-oncology agents, updates PD-L1 stratification criteria for Part 2A, clarifies screening biopsy criteria for Part 2A, and incorporates other clarifying modifications.                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 05 August 2019   | This is a revised protocol that defines the selected BMS-986249 + nivolumab doses and schedules for Part 2A Arms A - C, updates modified intermediate dose levels in Part 1B, and incorporates other minor clarifying edits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 15 November 2020 | This is a revised protocol to modify the treatment arms in the Part 2A Expansion Phase and define the Part 2B Expansion Phase. The Part 2A Expansion Phase will now include concurrent evaluation of 3 treatment arms in a randomized setting in melanoma (2 different dose regimens of BMS-986249 in combination with nivolumab and 1 standard-of-care reference arm) rather than the previously defined 5 treatment arms. The Part 2B Expansion Phase will evaluate a single-dose regimen of BMS-986248 in combination with nivolumab in 3 tumor-specific cohorts. This revision also includes global changes to reduce redundancies and increase readability, incorporates updated learnings for BMS-986249, nivolumab, and ipilimumab, and adds language around COVID-19. |
| 22 February 2022 | The primary reasons for Protocol Amendment 08 are to update and/or clarify the inclusion criteria to align with the current disease state and treatment landscape based on investigator feedback for Part 2.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

|               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 14 March 2023 | The overall rationale for this protocol amendment is to remove exploratory endpoints (modified RECIST version 1.1 for immune-based therapeutics [iRECIST] and severe acute respiratory syndrome coronavirus 2 [SARSCoV-2]); to introduce the option of also supplying sites with 10-mL vials containing 50 mg of ipilimumab; to decrease participant and site burden by reducing pharmacokinetic (PK), anti-drug antibody (ADA), and biomarker sample collections; and to add clarifying language. |
|---------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Notes:

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## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported