



## Clinical trial results:

### A Phase I/IIa Study of BMS 986148, a Mesothelin Directed Antibody Drug Conjugate, in Subjects with Select Advanced Solid Tumors

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2014-002485-70 |
| Trial protocol           | NL BE GB       |
| Global end of trial date | 07 May 2020    |

#### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1 (current)  |
| This version publication date  | 09 April 2022 |
| First version publication date | 09 April 2022 |

#### Trial information

##### Trial identification

|                       |           |
|-----------------------|-----------|
| Sponsor protocol code | CA008-002 |
|-----------------------|-----------|

##### Additional study identifiers

|                                    |                 |
|------------------------------------|-----------------|
| ISRCTN number                      | -               |
| ClinicalTrials.gov id (NCT number) | NCT02341625     |
| WHO universal trial number (UTN)   | U1111-1165-9742 |

Notes:

#### Sponsors

|                              |                                                                                                 |
|------------------------------|-------------------------------------------------------------------------------------------------|
| Sponsor organisation name    | Bristol-Myers Squibb                                                                            |
| Sponsor organisation address | Chaussée de la Hulpe 185, Brussels, Belgium, 1170                                               |
| Public contact               | EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com |
| Scientific contact           | Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@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 May 2020 |
| Is this the analysis of the primary completion data? | No          |
| Global end of trial reached?                         | Yes         |
| Global end of trial date                             | 07 May 2020 |
| Was the trial ended prematurely?                     | Yes         |

Notes:

## General information about the trial

Main objective of the trial:

To assess the safety and tolerability of BMS-986148 in subjects with select advanced solid tumors.

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 participants were followed.

Background therapy: -

Evidence for comparator: -

|                                                           |              |
|-----------------------------------------------------------|--------------|
| Actual start date of recruitment                          | 19 June 2015 |
| 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 | Netherlands: 13   |
| Country: Number of subjects enrolled | United Kingdom: 1 |
| Country: Number of subjects enrolled | Belgium: 30       |
| Country: Number of subjects enrolled | Italy: 9          |
| Country: Number of subjects enrolled | Australia: 23     |
| Country: Number of subjects enrolled | Canada: 28        |
| Country: Number of subjects enrolled | United States: 22 |
| Worldwide total number of subjects   | 126               |
| EEA total number of subjects         | 52                |

Notes:

### Subjects enrolled per age group

|                                           |   |
|-------------------------------------------|---|
| 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)      | 73 |
| From 65 to 84 years       | 53 |
| 85 years and over         | 0  |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

126 participants 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>             | BMS-986148 0.1MG/KG Q3W |

Arm description:

Part 1A Dose Escalation: BMS-986148 0.1 mg/kg IV Q3W in a 21-day cycle

|                                        |                 |
|----------------------------------------|-----------------|
| Arm type                               | Experimental    |
| Investigational medicinal product name | BMS-986148      |
| Investigational medicinal product code |                 |
| Other name                             |                 |
| Pharmaceutical forms                   | Injection       |
| Routes of administration               | Intravenous use |

Dosage and administration details:

0.1MG/KG Q3W infused within 60 minutes

|                  |                         |
|------------------|-------------------------|
| <b>Arm title</b> | BMS-986148 0.2MG/KG Q3W |
|------------------|-------------------------|

Arm description:

Part 1A Dose Escalation: BMS-986148 0.2 mg/kg IV Q3W in a 21-day cycle

|                                        |                 |
|----------------------------------------|-----------------|
| Arm type                               | Experimental    |
| Investigational medicinal product name | BMS-986148      |
| Investigational medicinal product code |                 |
| Other name                             |                 |
| Pharmaceutical forms                   | Injection       |
| Routes of administration               | Intravenous use |

Dosage and administration details:

0.2MG/KG Q3W infused within 60 minutes

|                  |                         |
|------------------|-------------------------|
| <b>Arm title</b> | BMS-986148 0.4MG/KG Q3W |
|------------------|-------------------------|

Arm description:

Part 1A Dose Escalation: BMS-986148 0.4 mg/kg IV Q3W in a 21-day cycle

|                                        |                 |
|----------------------------------------|-----------------|
| Arm type                               | Experimental    |
| Investigational medicinal product name | BMS-986148      |
| Investigational medicinal product code |                 |
| Other name                             |                 |
| Pharmaceutical forms                   | Injection       |
| Routes of administration               | Intravenous use |

Dosage and administration details:

0.4MG/KG Q3W infused within 60 minutes

|                  |                         |
|------------------|-------------------------|
| <b>Arm title</b> | BMS-986148 0.8MG/KG Q3W |
|------------------|-------------------------|

|                                                                                                                                                                |                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Arm description:                                                                                                                                               |                            |
| Part 1A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W in a 21-day cycle                                                                                         |                            |
| Arm type                                                                                                                                                       | Experimental               |
| Investigational medicinal product name                                                                                                                         | BMS-986148                 |
| Investigational medicinal product code                                                                                                                         |                            |
| Other name                                                                                                                                                     |                            |
| Pharmaceutical forms                                                                                                                                           | Injection                  |
| Routes of administration                                                                                                                                       | Intravenous use            |
| Dosage and administration details:                                                                                                                             |                            |
| 0.8MG/KG Q3W infused within 60 minutes                                                                                                                         |                            |
| <b>Arm title</b>                                                                                                                                               | BMS-986148 1.2MG/KG Q3W Es |
| Arm description:                                                                                                                                               |                            |
| Part 1A Dose Escalation BMS-986148 1.2 mg/kg IV Q3W                                                                                                            |                            |
| Arm type                                                                                                                                                       | Experimental               |
| Investigational medicinal product name                                                                                                                         | BMS-986148                 |
| Investigational medicinal product code                                                                                                                         |                            |
| Other name                                                                                                                                                     |                            |
| Pharmaceutical forms                                                                                                                                           | Injection                  |
| Routes of administration                                                                                                                                       | Intravenous use            |
| Dosage and administration details:                                                                                                                             |                            |
| 1.2MG/KG Q3W infused within 60 minutes                                                                                                                         |                            |
| <b>Arm title</b>                                                                                                                                               | BMS-986148 1.6MG/KG Q3W    |
| Arm description:                                                                                                                                               |                            |
| Part 1A Dose Escalation: BMS-986148 1.6 mg/kg IV Q3W in a 21-day cycle                                                                                         |                            |
| Arm type                                                                                                                                                       | Experimental               |
| Investigational medicinal product name                                                                                                                         | BMS-986148                 |
| Investigational medicinal product code                                                                                                                         |                            |
| Other name                                                                                                                                                     |                            |
| Pharmaceutical forms                                                                                                                                           | Injection                  |
| Routes of administration                                                                                                                                       | Intravenous use            |
| Dosage and administration details:                                                                                                                             |                            |
| 1.6MG/KG Q3W infused within 60 minutes                                                                                                                         |                            |
| <b>Arm title</b>                                                                                                                                               | BMS-986148 1.2MG/KG Q3W Ex |
| Arm description:                                                                                                                                               |                            |
| Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer |                            |
| Arm type                                                                                                                                                       | Experimental               |
| Investigational medicinal product name                                                                                                                         | BMS-986148                 |
| Investigational medicinal product code                                                                                                                         |                            |
| Other name                                                                                                                                                     |                            |
| Pharmaceutical forms                                                                                                                                           | Injection                  |
| Routes of administration                                                                                                                                       | Intravenous use            |
| Dosage and administration details:                                                                                                                             |                            |
| 1.2MG/KG Q3W infused within 60 minutes                                                                                                                         |                            |
| <b>Arm title</b>                                                                                                                                               | BMS-986148 0.4MG/KG QW     |
| Arm description:                                                                                                                                               |                            |
| Part 1B Dose Escalation: BMS-986148 0.4 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle                                                               |                            |
| Arm type                                                                                                                                                       | Experimental               |

|                                        |                 |
|----------------------------------------|-----------------|
| Investigational medicinal product name | BMS-986148      |
| Investigational medicinal product code |                 |
| Other name                             |                 |
| Pharmaceutical forms                   | Injection       |
| Routes of administration               | Intravenous use |

Dosage and administration details:

0.4 MG/KG QW infused within 60 minutes

|                  |                        |
|------------------|------------------------|
| <b>Arm title</b> | BMS-986148 0.6MG/KG QW |
|------------------|------------------------|

Arm description:

Part 1B Dose Escalation: BMS-986148 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle

|                                        |                 |
|----------------------------------------|-----------------|
| Arm type                               | Experimental    |
| Investigational medicinal product name | BMS-986148      |
| Investigational medicinal product code |                 |
| Other name                             |                 |
| Pharmaceutical forms                   | Injection       |
| Routes of administration               | Intravenous use |

Dosage and administration details:

0.6 MG/KG QW infused within 60 minutes

|                  |                                   |
|------------------|-----------------------------------|
| <b>Arm title</b> | BMS-986148 0.8MG/KG Q3W+Nivolumab |
|------------------|-----------------------------------|

Arm description:

Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle

Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

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

Dosage and administration details:

360mg as a 30-minute infusion on Day 1 of each 21-day treatment cycle

|                                        |                 |
|----------------------------------------|-----------------|
| Investigational medicinal product name | BMS-986148      |
| Investigational medicinal product code |                 |
| Other name                             |                 |
| Pharmaceutical forms                   | Injection       |
| Routes of administration               | Intravenous use |

Dosage and administration details:

0.8 MG/KG QW infused within 60 minutes

| <b>Number of subjects in period 1</b>              | <b>BMS-986148<br/>0.1MG/KG Q3W</b> | <b>BMS-986148<br/>0.2MG/KG Q3W</b> | <b>BMS-986148<br/>0.4MG/KG Q3W</b> |
|----------------------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| Started                                            | 2                                  | 2                                  | 3                                  |
| Completed                                          | 0                                  | 0                                  | 0                                  |
| Not completed                                      | 2                                  | 2                                  | 3                                  |
| Not Reported                                       | -                                  | -                                  | -                                  |
| Other Reasons                                      | -                                  | -                                  | -                                  |
| Participant Request to Discontinue Study Treatment | -                                  | -                                  | -                                  |

|                                       |   |   |   |
|---------------------------------------|---|---|---|
| Completed Treatment as per Protocol   | - | - | - |
| Adverse Event Unrelated to Study Drug | - | - | - |
| Study Drug Toxicity                   | - | - | - |
| Participant Withdrew Consent          | - | - | - |
| Disease Progression                   | 2 | 2 | 3 |

| <b>Number of subjects in period 1</b>              | <b>BMS-986148<br/>0.8MG/KG Q3W</b> | <b>BMS-986148<br/>1.2MG/KG Q3W Es</b> | <b>BMS-986148<br/>1.6MG/KG Q3W</b> |
|----------------------------------------------------|------------------------------------|---------------------------------------|------------------------------------|
| Started                                            | 8                                  | 8                                     | 10                                 |
| Completed                                          | 0                                  | 0                                     | 0                                  |
| Not completed                                      | 8                                  | 8                                     | 10                                 |
| Not Reported                                       | -                                  | -                                     | -                                  |
| Other Reasons                                      | -                                  | 1                                     | -                                  |
| Participant Request to Discontinue Study Treatment | -                                  | -                                     | -                                  |
| Completed Treatment as per Protocol                | -                                  | -                                     | -                                  |
| Adverse Event Unrelated to Study Drug              | -                                  | -                                     | -                                  |
| Study Drug Toxicity                                | 1                                  | -                                     | 3                                  |
| Participant Withdrew Consent                       | 1                                  | -                                     | -                                  |
| Disease Progression                                | 6                                  | 7                                     | 7                                  |

| <b>Number of subjects in period 1</b>              | <b>BMS-986148<br/>1.2MG/KG Q3W Ex</b> | <b>BMS-986148<br/>0.4MG/KG QW</b> | <b>BMS-986148<br/>0.6MG/KG QW</b> |
|----------------------------------------------------|---------------------------------------|-----------------------------------|-----------------------------------|
| Started                                            | 51                                    | 8                                 | 4                                 |
| Completed                                          | 0                                     | 0                                 | 0                                 |
| Not completed                                      | 51                                    | 8                                 | 4                                 |
| Not Reported                                       | -                                     | -                                 | -                                 |
| Other Reasons                                      | 5                                     | -                                 | -                                 |
| Participant Request to Discontinue Study Treatment | 6                                     | 2                                 | -                                 |
| Completed Treatment as per Protocol                | -                                     | -                                 | -                                 |
| Adverse Event Unrelated to Study Drug              | 2                                     | 1                                 | -                                 |
| Study Drug Toxicity                                | 10                                    | -                                 | -                                 |
| Participant Withdrew Consent                       | -                                     | -                                 | -                                 |
| Disease Progression                                | 28                                    | 5                                 | 4                                 |

| <b>Number of subjects in period 1</b> | <b>BMS-986148<br/>0.8MG/KG<br/>Q3W+Nivolumab</b> |
|---------------------------------------|--------------------------------------------------|
| Started                               | 30                                               |
| Completed                             | 0                                                |
| Not completed                         | 30                                               |
| Not Reported                          | 3                                                |
| Other Reasons                         | 2                                                |

|                                                    |    |
|----------------------------------------------------|----|
| Participant Request to Discontinue Study Treatment | -  |
| Completed Treatment as per Protocol                | 1  |
| Adverse Event Unrelated to Study Drug              | 2  |
| Study Drug Toxicity                                | 3  |
| Participant Withdrew Consent                       | -  |
| Disease Progression                                | 19 |

## Baseline characteristics

| Reporting groups                                                                                                                                                                       |                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Reporting group title                                                                                                                                                                  | BMS-986148 0.1MG/KG Q3W           |
| Reporting group description:                                                                                                                                                           |                                   |
| Part 1A Dose Escalation: BMS-986148 0.1 mg/kg IV Q3W in a 21-day cycle                                                                                                                 |                                   |
| Reporting group title                                                                                                                                                                  | BMS-986148 0.2MG/KG Q3W           |
| Reporting group description:                                                                                                                                                           |                                   |
| Part 1A Dose Escalation: BMS-986148 0.2 mg/kg IV Q3W in a 21-day cycle                                                                                                                 |                                   |
| Reporting group title                                                                                                                                                                  | BMS-986148 0.4MG/KG Q3W           |
| Reporting group description:                                                                                                                                                           |                                   |
| Part 1A Dose Escalation: BMS-986148 0.4 mg/kg IV Q3W in a 21-day cycle                                                                                                                 |                                   |
| Reporting group title                                                                                                                                                                  | BMS-986148 0.8MG/KG Q3W           |
| Reporting group description:                                                                                                                                                           |                                   |
| Part 1A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W in a 21-day cycle                                                                                                                 |                                   |
| Reporting group title                                                                                                                                                                  | BMS-986148 1.2MG/KG Q3W Es        |
| Reporting group description:                                                                                                                                                           |                                   |
| Part 1A Dose Escalation BMS-986148 1.2 mg/kg IV Q3W                                                                                                                                    |                                   |
| Reporting group title                                                                                                                                                                  | BMS-986148 1.6MG/KG Q3W           |
| Reporting group description:                                                                                                                                                           |                                   |
| Part 1A Dose Escalation: BMS-986148 1.6 mg/kg IV Q3W in a 21-day cycle                                                                                                                 |                                   |
| Reporting group title                                                                                                                                                                  | BMS-986148 1.2MG/KG Q3W Ex        |
| Reporting group description:                                                                                                                                                           |                                   |
| Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer                         |                                   |
| Reporting group title                                                                                                                                                                  | BMS-986148 0.4MG/KG QW            |
| Reporting group description:                                                                                                                                                           |                                   |
| Part 1B Dose Escalation: BMS-986148 0.4 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle                                                                                       |                                   |
| Reporting group title                                                                                                                                                                  | BMS-986148 0.6MG/KG QW            |
| Reporting group description:                                                                                                                                                           |                                   |
| Part 1B Dose Escalation: BMS-986148 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle                                                                                       |                                   |
| Reporting group title                                                                                                                                                                  | BMS-986148 0.8MG/KG Q3W+Nivolumab |
| Reporting group description:                                                                                                                                                           |                                   |
| Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle                                                                                          |                                   |
| Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer |                                   |

| Reporting group values                                | BMS-986148<br>0.1MG/KG Q3W | BMS-986148<br>0.2MG/KG Q3W | BMS-986148<br>0.4MG/KG Q3W |
|-------------------------------------------------------|----------------------------|----------------------------|----------------------------|
| Number of subjects                                    | 2                          | 2                          | 3                          |
| Age categorical                                       |                            |                            |                            |
| Units: Subjects                                       |                            |                            |                            |
| In utero                                              | 0                          | 0                          | 0                          |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0                          | 0                          | 0                          |
| Newborns (0-27 days)                                  | 0                          | 0                          | 0                          |
| Infants and toddlers (28 days-23<br>months)           | 0                          | 0                          | 0                          |
| Children (2-11 years)                                 | 0                          | 0                          | 0                          |
| Adolescents (12-17 years)                             | 0                          | 0                          | 0                          |
| Adults (18-64 years)                                  | 2                          | 0                          | 2                          |

|                                           |       |       |       |
|-------------------------------------------|-------|-------|-------|
| From 65-84 years                          | 0     | 2     | 1     |
| 85 years and over                         | 0     | 0     | 0     |
|                                           |       |       |       |
| Age Continuous                            |       |       |       |
| Units: Years                              |       |       |       |
| arithmetic mean                           | 59.5  | 70.5  | 65.3  |
| standard deviation                        | ± 0.7 | ± 0.7 | ± 5.8 |
| Sex: Female, Male                         |       |       |       |
| Units: Participants                       |       |       |       |
| Female                                    | 0     | 0     | 2     |
| Male                                      | 2     | 2     | 1     |
| Race (NIH/OMB)                            |       |       |       |
| Units: Subjects                           |       |       |       |
| American Indian or Alaska Native          | 0     | 0     | 0     |
| Asian                                     | 1     | 0     | 0     |
| Native Hawaiian or Other Pacific Islander | 0     | 0     | 0     |
| Black or African American                 | 0     | 0     | 0     |
| White                                     | 1     | 2     | 3     |
| More than one race                        | 0     | 0     | 0     |
| Unknown or Not Reported                   | 0     | 0     | 0     |
| Ethnicity (NIH/OMB)                       |       |       |       |
| Units: Subjects                           |       |       |       |
| Hispanic or Latino                        | 0     | 1     | 0     |
| Not Hispanic or Latino                    | 2     | 1     | 3     |
| Unknown or Not Reported                   | 0     | 0     | 0     |

| <b>Reporting group values</b>                         | <b>BMS-986148<br/>0.8MG/KG Q3W</b> | <b>BMS-986148<br/>1.2MG/KG Q3W Es</b> | <b>BMS-986148<br/>1.6MG/KG Q3W</b> |
|-------------------------------------------------------|------------------------------------|---------------------------------------|------------------------------------|
| Number of subjects                                    | 8                                  | 8                                     | 10                                 |
| Age categorical                                       |                                    |                                       |                                    |
| Units: Subjects                                       |                                    |                                       |                                    |
| In utero                                              | 0                                  | 0                                     | 0                                  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0                                  | 0                                     | 0                                  |
| Newborns (0-27 days)                                  | 0                                  | 0                                     | 0                                  |
| Infants and toddlers (28 days-23<br>months)           | 0                                  | 0                                     | 0                                  |
| Children (2-11 years)                                 | 0                                  | 0                                     | 0                                  |
| Adolescents (12-17 years)                             | 0                                  | 0                                     | 0                                  |
| Adults (18-64 years)                                  | 4                                  | 5                                     | 7                                  |
| From 65-84 years                                      | 4                                  | 3                                     | 3                                  |
| 85 years and over                                     | 0                                  | 0                                     | 0                                  |
| Age Continuous                                        |                                    |                                       |                                    |
| Units: Years                                          |                                    |                                       |                                    |
| arithmetic mean                                       | 63.9                               | 63.4                                  | 59.0                               |
| standard deviation                                    | ± 5.4                              | ± 5.1                                 | ± 16.0                             |
| Sex: Female, Male                                     |                                    |                                       |                                    |
| Units: Participants                                   |                                    |                                       |                                    |
| Female                                                | 3                                  | 3                                     | 3                                  |
| Male                                                  | 5                                  | 5                                     | 7                                  |

|                                           |   |   |    |
|-------------------------------------------|---|---|----|
| Race (NIH/OMB)                            |   |   |    |
| Units: Subjects                           |   |   |    |
| American Indian or Alaska Native          | 0 | 0 | 0  |
| Asian                                     | 1 | 1 | 1  |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0  |
| Black or African American                 | 0 | 0 | 0  |
| White                                     | 7 | 7 | 9  |
| More than one race                        | 0 | 0 | 0  |
| Unknown or Not Reported                   | 0 | 0 | 0  |
| Ethnicity (NIH/OMB)                       |   |   |    |
| Units: Subjects                           |   |   |    |
| Hispanic or Latino                        | 0 | 0 | 0  |
| Not Hispanic or Latino                    | 8 | 8 | 10 |
| Unknown or Not Reported                   | 0 | 0 | 0  |

| Reporting group values                                | BMS-986148<br>1.2MG/KG Q3W Ex | BMS-986148<br>0.4MG/KG QW | BMS-986148<br>0.6MG/KG QW |
|-------------------------------------------------------|-------------------------------|---------------------------|---------------------------|
| Number of subjects                                    | 51                            | 8                         | 4                         |
| Age categorical                                       |                               |                           |                           |
| Units: Subjects                                       |                               |                           |                           |
| In utero                                              | 0                             | 0                         | 0                         |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0                             | 0                         | 0                         |
| Newborns (0-27 days)                                  | 0                             | 0                         | 0                         |
| Infants and toddlers (28 days-23 months)              | 0                             | 0                         | 0                         |
| Children (2-11 years)                                 | 0                             | 0                         | 0                         |
| Adolescents (12-17 years)                             | 0                             | 0                         | 0                         |
| Adults (18-64 years)                                  | 27                            | 4                         | 3                         |
| From 65-84 years                                      | 24                            | 4                         | 1                         |
| 85 years and over                                     | 0                             | 0                         | 0                         |
| Age Continuous                                        |                               |                           |                           |
| Units: Years                                          |                               |                           |                           |
| arithmetic mean                                       | 61.5                          | 66.3                      | 64.5                      |
| standard deviation                                    | ± 9.5                         | ± 8.6                     | ± 9.1                     |
| Sex: Female, Male                                     |                               |                           |                           |
| Units: Participants                                   |                               |                           |                           |
| Female                                                | 31                            | 3                         | 2                         |
| Male                                                  | 20                            | 5                         | 2                         |
| 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                             | 2                             | 0                         | 1                         |
| White                                                 | 46                            | 8                         | 3                         |
| More than one race                                    | 0                             | 0                         | 0                         |
| Unknown or Not Reported                               | 3                             | 0                         | 0                         |
| Ethnicity (NIH/OMB)                                   |                               |                           |                           |
| Units: Subjects                                       |                               |                           |                           |
| Hispanic or Latino                                    | 0                             | 0                         | 0                         |

|                         |    |   |   |
|-------------------------|----|---|---|
| Not Hispanic or Latino  | 46 | 8 | 3 |
| Unknown or Not Reported | 5  | 0 | 1 |

| <b>Reporting group values</b>                         | <b>BMS-986148<br/>0.8MG/KG<br/>Q3W+Nivolumab</b> | <b>Total</b> |  |
|-------------------------------------------------------|--------------------------------------------------|--------------|--|
| Number of subjects                                    | 30                                               | 126          |  |
| Age categorical<br>Units: Subjects                    |                                                  |              |  |
| In utero                                              | 0                                                | 0            |  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0                                                | 0            |  |
| Newborns (0-27 days)                                  | 0                                                | 0            |  |
| Infants and toddlers (28 days-23 months)              | 0                                                | 0            |  |
| Children (2-11 years)                                 | 0                                                | 0            |  |
| Adolescents (12-17 years)                             | 0                                                | 0            |  |
| Adults (18-64 years)                                  | 19                                               | 73           |  |
| From 65-84 years                                      | 11                                               | 53           |  |
| 85 years and over                                     | 0                                                | 0            |  |
| Age Continuous<br>Units: Years                        |                                                  |              |  |
| arithmetic mean                                       | 61.6                                             |              |  |
| standard deviation                                    | ± 9.4                                            | -            |  |
| Sex: Female, Male<br>Units: Participants              |                                                  |              |  |
| Female                                                | 12                                               | 59           |  |
| Male                                                  | 18                                               | 67           |  |
| Race (NIH/OMB)<br>Units: Subjects                     |                                                  |              |  |
| American Indian or Alaska Native                      | 0                                                | 0            |  |
| Asian                                                 | 0                                                | 4            |  |
| Native Hawaiian or Other Pacific Islander             | 0                                                | 0            |  |
| Black or African American                             | 0                                                | 3            |  |
| White                                                 | 30                                               | 116          |  |
| More than one race                                    | 0                                                | 0            |  |
| Unknown or Not Reported                               | 0                                                | 3            |  |
| Ethnicity (NIH/OMB)<br>Units: Subjects                |                                                  |              |  |
| Hispanic or Latino                                    | 0                                                | 1            |  |
| Not Hispanic or Latino                                | 25                                               | 114          |  |
| Unknown or Not Reported                               | 5                                                | 11           |  |

## End points

### End points reporting groups

|                                                                                                                                                                                                                        |                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Reporting group title                                                                                                                                                                                                  | BMS-986148 0.1MG/KG Q3W           |
| Reporting group description:                                                                                                                                                                                           |                                   |
| Part 1A Dose Escalation: BMS-986148 0.1 mg/kg IV Q3W in a 21-day cycle                                                                                                                                                 |                                   |
| Reporting group title                                                                                                                                                                                                  | BMS-986148 0.2MG/KG Q3W           |
| Reporting group description:                                                                                                                                                                                           |                                   |
| Part 1A Dose Escalation: BMS-986148 0.2 mg/kg IV Q3W in a 21-day cycle                                                                                                                                                 |                                   |
| Reporting group title                                                                                                                                                                                                  | BMS-986148 0.4MG/KG Q3W           |
| Reporting group description:                                                                                                                                                                                           |                                   |
| Part 1A Dose Escalation: BMS-986148 0.4 mg/kg IV Q3W in a 21-day cycle                                                                                                                                                 |                                   |
| Reporting group title                                                                                                                                                                                                  | BMS-986148 0.8MG/KG Q3W           |
| Reporting group description:                                                                                                                                                                                           |                                   |
| Part 1A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W in a 21-day cycle                                                                                                                                                 |                                   |
| Reporting group title                                                                                                                                                                                                  | BMS-986148 1.2MG/KG Q3W Es        |
| Reporting group description:                                                                                                                                                                                           |                                   |
| Part 1A Dose Escalation BMS-986148 1.2 mg/kg IV Q3W                                                                                                                                                                    |                                   |
| Reporting group title                                                                                                                                                                                                  | BMS-986148 1.6MG/KG Q3W           |
| Reporting group description:                                                                                                                                                                                           |                                   |
| Part 1A Dose Escalation: BMS-986148 1.6 mg/kg IV Q3W in a 21-day cycle                                                                                                                                                 |                                   |
| Reporting group title                                                                                                                                                                                                  | BMS-986148 1.2MG/KG Q3W Ex        |
| Reporting group description:                                                                                                                                                                                           |                                   |
| Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer                                                         |                                   |
| Reporting group title                                                                                                                                                                                                  | BMS-986148 0.4MG/KG QW            |
| Reporting group description:                                                                                                                                                                                           |                                   |
| Part 1B Dose Escalation: BMS-986148 0.4 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle                                                                                                                       |                                   |
| Reporting group title                                                                                                                                                                                                  | BMS-986148 0.6MG/KG QW            |
| Reporting group description:                                                                                                                                                                                           |                                   |
| Part 1B Dose Escalation: BMS-986148 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle                                                                                                                       |                                   |
| Reporting group title                                                                                                                                                                                                  | BMS-986148 0.8MG/KG Q3W+Nivolumab |
| Reporting group description:                                                                                                                                                                                           |                                   |
| Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle                                                                                                                          |                                   |
| Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer                                 |                                   |
| Subject analysis set title                                                                                                                                                                                             | BMS-986148 1.2MG/KG Q3W Es        |
| Subject analysis set type                                                                                                                                                                                              | Full analysis                     |
| Subject analysis set description:                                                                                                                                                                                      |                                   |
| Part 1A Dose Escalation BMS-986148 1.2 mg/kg IV Q3W and Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer |                                   |
| Subject analysis set title                                                                                                                                                                                             | BMS 1.2MG/KG Q3W Ex               |
| Subject analysis set type                                                                                                                                                                                              | Full analysis                     |
| Subject analysis set description:                                                                                                                                                                                      |                                   |
| Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer                                                         |                                   |
| Subject analysis set title                                                                                                                                                                                             | BMS 0.8MG/KG Q3W+Nivolumab Es     |
| Subject analysis set type                                                                                                                                                                                              | Full analysis                     |
| Subject analysis set description:                                                                                                                                                                                      |                                   |
| Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle                                                                                                                          |                                   |
| Subject analysis set title                                                                                                                                                                                             | BMS 0.8MG/KG Q3W+Nivolumab Ex     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                          | Full analysis                     |
| Subject analysis set description:                                                                                                                                                                                                                                                                                                                                                                                                                  |                                   |
| Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer                                                                                                                                                                                                                                                             |                                   |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                         | BMS-986148 Mesothelioma           |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                          | Full analysis                     |
| Subject analysis set description:                                                                                                                                                                                                                                                                                                                                                                                                                  |                                   |
| Part 1A Dose Escalation: BMS-986148 starting with a dose of 0.1 mg/kg IV Q3W to a dose of 1.6 mg/kg IV Q3W in a 21-day cycle Part 1B Dose Escalation: BMS-986148 starting with a dose of 0.4 mg/kg IV QW to a dose of 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer  |                                   |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                         | BMS-986148+Nivolumab Mesothelioma |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                          | Full analysis                     |
| Subject analysis set description:                                                                                                                                                                                                                                                                                                                                                                                                                  |                                   |
| Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer                                                                                                                                                               |                                   |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                         | BMS-986148 Ovarian                |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                          | Full analysis                     |
| Subject analysis set description:                                                                                                                                                                                                                                                                                                                                                                                                                  |                                   |
| Part 1A Dose Escalation: BMS-986148 starting with a dose of 0.1 mg/kg IV Q3W to a dose of 1.6 mg/kg IV Q3W in a 21-day cycle Part 1B Dose Escalation: BMS-986148 starting with a dose of 0.4 mg/kg IV QW to a dose of 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer. |                                   |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                         | BMS-986148+Nivolumab Ovarian      |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                          | Full analysis                     |
| Subject analysis set description:                                                                                                                                                                                                                                                                                                                                                                                                                  |                                   |
| Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer                                                                                                                                                               |                                   |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                         | BMS-986148 Pancreatic             |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                          | Full analysis                     |
| Subject analysis set description:                                                                                                                                                                                                                                                                                                                                                                                                                  |                                   |
| Part 1A Dose Escalation: BMS-986148 starting with a dose of 0.8 mg/kg IV Q3W to a dose of 1.6 mg/kg IV Q3W in a 21-day cycle Part 1B Dose Escalation: BMS-986148 starting with a dose of 0.4 mg/kg IV QW to a dose of 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer. |                                   |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                         | BMS-986148+Nivolumab Pancreatic   |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                          | Full analysis                     |
| Subject analysis set description:                                                                                                                                                                                                                                                                                                                                                                                                                  |                                   |
| Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer                                                                                                                                                               |                                   |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                         | BMS-986148 NSCLC                  |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                          | Full analysis                     |
| Subject analysis set description:                                                                                                                                                                                                                                                                                                                                                                                                                  |                                   |
| Part 1A Dose Escalation: BMS-986148 starting with a dose of 0.8 mg/kg IV Q3W to a dose of 1.6 mg/kg IV Q3W in a 21-day cycle Part 1B Dose Escalation: BMS-986148 starting with a dose of 0.4 mg/kg IV QW to a dose of 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer. |                                   |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                                         | BMS-986148+Nivolumab NSCLC        |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                                          | Full analysis                     |
| Subject analysis set description:                                                                                                                                                                                                                                                                                                                                                                                                                  |                                   |
| Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five                                                                                                                                                                                                                                                        |                                   |

tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

|                            |                    |
|----------------------------|--------------------|
| Subject analysis set title | BMS-986148 Gastric |
| Subject analysis set type  | Full analysis      |

Subject analysis set description:

Part 1A Dose Escalation: BMS-986148 starting with a dose of 0.8 mg/kg IV Q3W to a dose of 1.6 mg/kg IV Q3W in a 21-day cycle Part 1B Dose Escalation: BMS-986148 starting with a dose of 0.4 mg/kg IV QW to a dose of 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

|                            |                              |
|----------------------------|------------------------------|
| Subject analysis set title | BMS-986148+Nivolumab Gastric |
| Subject analysis set type  | Full analysis                |

Subject analysis set description:

Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

### Primary: Incidence of Participants with Adverse Events at Worst CTC Grade

|                 |                                                                                    |
|-----------------|------------------------------------------------------------------------------------|
| End point title | Incidence of Participants with Adverse Events at Worst CTC Grade <sup>[1][2]</sup> |
|-----------------|------------------------------------------------------------------------------------|

End point description:

Incidence of participants with adverse events at worst CTC grade including any grade adverse events (AEs), serious adverse events (SAEs), adverse events leading to discontinuations, and deaths grouped by dose + dose regimen.

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

End point timeframe:

From first dose to up to 100 days post last dose (Up to 6 months)

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: Only summary statistics planned 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: Baseline period arm is reported within the subject analysis set

| End point values               | BMS-986148<br>0.1MG/KG<br>Q3W | BMS-986148<br>0.2MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG<br>Q3W | BMS-986148<br>0.8MG/KG<br>Q3W |
|--------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Subject group type             | Reporting group               | Reporting group               | Reporting group               | Reporting group               |
| Number of subjects analysed    | 2                             | 2                             | 3                             | 8                             |
| Units: Participants            |                               |                               |                               |                               |
| Adverse Events (AEs)           | 1                             | 2                             | 3                             | 8                             |
| Serious Adverse Events (SAEs)  | 1                             | 1                             | 1                             | 5                             |
| AEs Leading to Discontinuation | 0                             | 0                             | 0                             | 1                             |
| Deaths                         | 1                             | 2                             | 3                             | 5                             |

| End point values              | BMS-986148<br>1.6MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG QW | BMS-986148<br>0.6MG/KG QW | BMS-986148<br>0.8MG/KG<br>Q3W+Nivolumab |
|-------------------------------|-------------------------------|---------------------------|---------------------------|-----------------------------------------|
| Subject group type            | Reporting group               | Reporting group           | Reporting group           | Reporting group                         |
| Number of subjects analysed   | 10                            | 8                         | 4                         | 30                                      |
| Units: Participants           |                               |                           |                           |                                         |
| Adverse Events (AEs)          | 10                            | 8                         | 4                         | 30                                      |
| Serious Adverse Events (SAEs) | 4                             | 6                         | 3                         | 21                                      |

|                                |   |   |   |    |
|--------------------------------|---|---|---|----|
| AEs Leading to Discontinuation | 3 | 1 | 0 | 7  |
| Deaths                         | 7 | 7 | 4 | 22 |

|                                |                                  |  |  |  |
|--------------------------------|----------------------------------|--|--|--|
| <b>End point values</b>        | BMS-986148<br>1.2MG/KG<br>Q3W Es |  |  |  |
| Subject group type             | Subject analysis set             |  |  |  |
| Number of subjects analysed    | 59                               |  |  |  |
| Units: Participants            |                                  |  |  |  |
| Adverse Events (AEs)           | 59                               |  |  |  |
| Serious Adverse Events (SAEs)  | 32                               |  |  |  |
| AEs Leading to Discontinuation | 11                               |  |  |  |
| Deaths                         | 38                               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants with Laboratory Test Toxicity Grade Shifting from Baseline

|                 |                                                                                                                 |
|-----------------|-----------------------------------------------------------------------------------------------------------------|
| End point title | Number of Participants with Laboratory Test Toxicity Grade Shifting from Baseline <sup>[3]</sup> <sup>[4]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------|

End point description:

Number of participants with laboratory test toxicity grade (Grade 0, 1, 2, 3, and 4) in hematology and chemistry shifting from baseline. An increase in baseline indicates a shift of participant to a greater toxicity grade. A decrease in baseline indicates a shift of participant to a lesser toxicity grade. Participants are grouped by dose + dose regimen assessed by NCT CTCAE V 4.03.

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

End point timeframe:

From first dose to up to 100 days post last dose (Up to 6 months)

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: Only summary statistics planned 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: Baseline period arm is reported within the subject analysis set

|                                       |                               |                               |                               |                               |
|---------------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| <b>End point values</b>               | BMS-986148<br>0.1MG/KG<br>Q3W | BMS-986148<br>0.2MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG<br>Q3W | BMS-986148<br>0.8MG/KG<br>Q3W |
| Subject group type                    | Reporting group               | Reporting group               | Reporting group               | Reporting group               |
| Number of subjects analysed           | 2                             | 2                             | 3                             | 8                             |
| Units: Participants                   |                               |                               |                               |                               |
| Hemoglobin increase from baseline     | 1                             | 1                             | 0                             | 3                             |
| Hemoglobin decrease from baseline     | 0                             | 0                             | 1                             | 1                             |
| Platelet Count increase from baseline | 0                             | 0                             | 0                             | 3                             |
| Platelet Count decrease from baseline | 0                             | 0                             | 0                             | 0                             |
| Leukocytes increase from baseline     | 0                             | 0                             | 1                             | 0                             |
| Leukocytes decrease from baseline     | 0                             | 0                             | 0                             | 0                             |

|                                              |   |   |   |   |
|----------------------------------------------|---|---|---|---|
| Neutrophils increase from baseline           | 0 | 0 | 0 | 0 |
| Neutrophils decrease from baseline           | 0 | 0 | 0 | 0 |
| Lymphocytes increase from baseline           | 1 | 2 | 1 | 3 |
| Lymphocytes decrease from baseline           | 0 | 0 | 1 | 0 |
| Absolute Neutrophil increase from baseline   | 0 | 0 | 0 | 0 |
| Absolute Neutrophil decrease from baseline   | 0 | 0 | 0 | 0 |
| ALP increase from baseline                   | 0 | 1 | 1 | 6 |
| ALP decrease from baseline                   | 0 | 0 | 0 | 0 |
| AST increase from baseline                   | 0 | 1 | 1 | 6 |
| AST decrease from baseline                   | 0 | 0 | 0 | 0 |
| ALT increase from baseline                   | 0 | 0 | 0 | 7 |
| ALT decrease from baseline                   | 0 | 0 | 0 | 0 |
| Bilirubin increase from baseline             | 0 | 1 | 0 | 2 |
| Bilirubin decrease from baseline             | 0 | 0 | 0 | 0 |
| Creatinine increase from baseline            | 0 | 0 | 1 | 2 |
| Creatinine decrease from baseline            | 0 | 0 | 0 | 0 |
| Sodium increase from baseline                | 0 | 1 | 1 | 4 |
| Sodium decrease from baseline                | 1 | 0 | 0 | 0 |
| Potassium increase from baseline             | 1 | 0 | 0 | 3 |
| Potassium decrease from baseline             | 0 | 1 | 0 | 0 |
| Calcium Total increase from baseline         | 0 | 0 | 0 | 5 |
| Calcium Total decrease from baseline         | 0 | 0 | 0 | 0 |
| Calcium Corrected increase from baseline     | 0 | 0 | 0 | 2 |
| Calcium Corrected decrease from baseline     | 0 | 0 | 0 | 0 |
| Phosphorus increase from baseline            | 2 | 0 | 2 | 3 |
| Phosphorus decrease from baseline            | 0 | 0 | 0 | 0 |
| Magnesium increase from baseline             | 0 | 1 | 1 | 2 |
| Magnesium decrease from baseline             | 0 | 0 | 0 | 0 |
| Glucose Fasting Serum increase from baseline | 0 | 0 | 0 | 0 |
| Glucose Fasting Serum decrease from baseline | 0 | 0 | 0 | 0 |
| Albumin increase from baseline               | 0 | 1 | 0 | 7 |
| Albumin decrease from baseline               | 0 | 0 | 0 | 0 |
| Amylase increase from baseline               | 0 | 0 | 0 | 0 |
| Amylase decrease from baseline               | 0 | 0 | 0 | 0 |
| Lipase increase from baseline                | 0 | 0 | 0 | 0 |
| Lipase decrease from baseline                | 0 | 0 | 0 | 0 |
| Creatine Kinase increase from baseline       | 0 | 0 | 1 | 0 |
| Creatine Kinase decrease from baseline       | 0 | 0 | 0 | 0 |
| Uric Acid increase from baseline             | 0 | 0 | 1 | 1 |
| Uric Acid decrease from baseline             | 0 | 0 | 0 | 0 |

|                         |                               |                           |                           |                                         |
|-------------------------|-------------------------------|---------------------------|---------------------------|-----------------------------------------|
| <b>End point values</b> | BMS-986148<br>1.6MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG QW | BMS-986148<br>0.6MG/KG QW | BMS-986148<br>0.8MG/KG<br>Q3W+Nivolumab |
|-------------------------|-------------------------------|---------------------------|---------------------------|-----------------------------------------|

| Subject group type                           | Reporting group | Reporting group | Reporting group | Reporting group |
|----------------------------------------------|-----------------|-----------------|-----------------|-----------------|
| Number of subjects analysed                  | 10              | 8               | 4               | 30              |
| Units: Participants                          |                 |                 |                 |                 |
| Hemoglobin increase from baseline            | 3               | 2               | 1               | 12              |
| Hemoglobin decrease from baseline            | 0               | 0               | 0               | 0               |
| Platelet Count increase from baseline        | 4               | 0               | 1               | 6               |
| Platelet Count decrease from baseline        | 0               | 0               | 0               | 0               |
| Leukocytes increase from baseline            | 2               | 1               | 0               | 2               |
| Leukocytes decrease from baseline            | 0               | 1               | 0               | 0               |
| Neutrophils increase from baseline           | 1               | 0               | 0               | 1               |
| Neutrophils decrease from baseline           | 0               | 0               | 0               | 0               |
| Lymphocytes increase from baseline           | 6               | 6               | 3               | 19              |
| Lymphocytes decrease from baseline           | 0               | 1               | 0               | 0               |
| Absolute Neutrophil increase from baseline   | 2               | 0               | 0               | 2               |
| Absolute Neutrophil decrease from baseline   | 0               | 0               | 0               | 0               |
| ALP increase from baseline                   | 10              | 5               | 4               | 24              |
| ALP decrease from baseline                   | 0               | 0               | 0               | 0               |
| AST increase from baseline                   | 10              | 6               | 4               | 26              |
| AST decrease from baseline                   | 0               | 0               | 0               | 0               |
| ALT increase from baseline                   | 10              | 5               | 3               | 25              |
| ALT decrease from baseline                   | 0               | 0               | 0               | 0               |
| Bilirubin increase from baseline             | 3               | 2               | 2               | 7               |
| Bilirubin decrease from baseline             | 0               | 0               | 0               | 0               |
| Creatinine increase from baseline            | 2               | 1               | 3               | 5               |
| Creatinine decrease from baseline            | 0               | 0               | 0               | 0               |
| Sodium increase from baseline                | 4               | 1               | 2               | 17              |
| Sodium decrease from baseline                | 0               | 0               | 0               | 0               |
| Potassium increase from baseline             | 5               | 1               | 2               | 9               |
| Potassium decrease from baseline             | 0               | 0               | 0               | 0               |
| Calcium Total increase from baseline         | 4               | 3               | 1               | 10              |
| Calcium Total decrease from baseline         | 0               | 0               | 0               | 1               |
| Calcium Corrected increase from baseline     | 1               | 0               | 0               | 1               |
| Calcium Corrected decrease from baseline     | 0               | 0               | 0               | 0               |
| Phosphorus increase from baseline            | 4               | 1               | 2               | 7               |
| Phosphorus decrease from baseline            | 0               | 1               | 0               | 0               |
| Magnesium increase from baseline             | 4               | 1               | 2               | 5               |
| Magnesium decrease from baseline             | 0               | 0               | 0               | 1               |
| Glucose Fasting Serum increase from baseline | 0               | 0               | 1               | 5               |
| Glucose Fasting Serum decrease from baseline | 0               | 0               | 0               | 1               |
| Albumin increase from baseline               | 8               | 6               | 2               | 19              |
| Albumin decrease from baseline               | 0               | 0               | 0               | 0               |
| Amylase increase from baseline               | 0               | 0               | 0               | 1               |
| Amylase decrease from baseline               | 0               | 0               | 0               | 0               |
| Lipase increase from baseline                | 0               | 0               | 0               | 1               |
| Lipase decrease from baseline                | 0               | 0               | 0               | 0               |
| Creatine Kinase increase from baseline       | 0               | 0               | 0               | 3               |
| Creatine Kinase decrease from baseline       | 0               | 0               | 0               | 0               |
| Uric Acid increase from baseline             | 2               | 0               | 2               | 6               |

|                                  |   |   |   |   |
|----------------------------------|---|---|---|---|
| Uric Acid decrease from baseline | 0 | 0 | 0 | 0 |
|----------------------------------|---|---|---|---|

|                                              |                                  |  |  |  |
|----------------------------------------------|----------------------------------|--|--|--|
| <b>End point values</b>                      | BMS-986148<br>1.2MG/KG<br>Q3W Es |  |  |  |
| Subject group type                           | Subject analysis set             |  |  |  |
| Number of subjects analysed                  | 59                               |  |  |  |
| Units: Participants                          |                                  |  |  |  |
| Hemoglobin increase from baseline            | 20                               |  |  |  |
| Hemoglobin decrease from baseline            | 3                                |  |  |  |
| Platelet Count increase from baseline        | 14                               |  |  |  |
| Platelet Count decrease from baseline        | 0                                |  |  |  |
| Leukocytes increase from baseline            | 1                                |  |  |  |
| Leukocytes decrease from baseline            | 1                                |  |  |  |
| Neutrophils increase from baseline           | 3                                |  |  |  |
| Neutrophils decrease from baseline           | 1                                |  |  |  |
| Lymphocytes increase from baseline           | 27                               |  |  |  |
| Lymphocytes decrease from baseline           | 0                                |  |  |  |
| Absolute Neutrophil increase from baseline   | 3                                |  |  |  |
| Absolute Neutrophil decrease from baseline   | 1                                |  |  |  |
| ALP increase from baseline                   | 46                               |  |  |  |
| ALP decrease from baseline                   | 0                                |  |  |  |
| AST increase from baseline                   | 53                               |  |  |  |
| AST decrease from baseline                   | 0                                |  |  |  |
| ALT increase from baseline                   | 50                               |  |  |  |
| ALT decrease from baseline                   | 1                                |  |  |  |
| Bilirubin increase from baseline             | 16                               |  |  |  |
| Bilirubin decrease from baseline             | 0                                |  |  |  |
| Creatinine increase from baseline            | 7                                |  |  |  |
| Creatinine decrease from baseline            | 0                                |  |  |  |
| Sodium increase from baseline                | 23                               |  |  |  |
| Sodium decrease from baseline                | 0                                |  |  |  |
| Potassium increase from baseline             | 24                               |  |  |  |
| Potassium decrease from baseline             | 3                                |  |  |  |
| Calcium Total increase from baseline         | 17                               |  |  |  |
| Calcium Total decrease from baseline         | 0                                |  |  |  |
| Calcium Corrected increase from baseline     | 0                                |  |  |  |
| Calcium Corrected decrease from baseline     | 0                                |  |  |  |
| Phosphorus increase from baseline            | 24                               |  |  |  |
| Phosphorus decrease from baseline            | 0                                |  |  |  |
| Magnesium increase from baseline             | 22                               |  |  |  |
| Magnesium decrease from baseline             | 3                                |  |  |  |
| Glucose Fasting Serum increase from baseline | 6                                |  |  |  |
| Glucose Fasting Serum decrease from baseline | 1                                |  |  |  |
| Albumin increase from baseline               | 37                               |  |  |  |
| Albumin decrease from baseline               | 0                                |  |  |  |

|                                        |   |  |  |  |
|----------------------------------------|---|--|--|--|
| Amylase increase from baseline         | 0 |  |  |  |
| Amylase decrease from baseline         | 0 |  |  |  |
| Lipase increase from baseline          | 0 |  |  |  |
| Lipase decrease from baseline          | 0 |  |  |  |
| Creatine Kinase increase from baseline | 9 |  |  |  |
| Creatine Kinase decrease from baseline | 1 |  |  |  |
| Uric Acid increase from baseline       | 6 |  |  |  |
| Uric Acid decrease from baseline       | 0 |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Maximum Observed Serum Concentration (Cmax)

|                 |                                                            |
|-----------------|------------------------------------------------------------|
| End point title | Maximum Observed Serum Concentration (Cmax) <sup>[5]</sup> |
|-----------------|------------------------------------------------------------|

End point description:

Maximum observed serum concentration (Cmax) of BMS-986148 grouped by dose + dose regimen.

Note: The geometric CV was not calculated. Arithmetic % CV is reported instead.

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

End point timeframe:

PK blood assessed on cycle 1, day 1

Notes:

[5] - 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: Baseline period arm is reported within the subject analysis set

| End point values                                    | BMS-986148<br>0.1MG/KG<br>Q3W | BMS-986148<br>0.2MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG<br>Q3W | BMS-986148<br>0.8MG/KG<br>Q3W |
|-----------------------------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Subject group type                                  | Reporting group               | Reporting group               | Reporting group               | Reporting group               |
| Number of subjects analysed                         | 2 <sup>[6]</sup>              | 2 <sup>[7]</sup>              | 3 <sup>[8]</sup>              | 8 <sup>[9]</sup>              |
| Units: ug/mL                                        |                               |                               |                               |                               |
| geometric mean (geometric coefficient of variation) |                               |                               |                               |                               |
| Total Antibody                                      | 2.3 (± 31.4)                  | 2.8 (± 7.6)                   | 3.3 (± 76.7)                  | 16.4 (± 47.2)                 |
| Active Antibody-Drug Conjugate (ADC)                | 2.0 (± 29.8)                  | 2.2 (± 8.2)                   | 2.6 (± 76.1)                  | 15.8 (± 46.4)                 |
| Unconjugated Tubulysin                              | 99999 (± 99999)               | 99999 (± 99999)               | 0.5 (± 99999)                 | 0.2 (± 17.1)                  |

Notes:

[6] - Unconjugated Tubulysin = 0 participants analyzed

[7] - Unconjugated Tubulysin = 0 participants analyzed

[8] - Unconjugated Tubulysin = 1 participants analyzed

[9] - Unconjugated Tubulysin = 4 participants analyzed

| End point values                                    | BMS-986148<br>1.2MG/KG<br>Q3W Es | BMS-986148<br>1.6MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG QW | BMS-986148<br>0.6MG/KG QW |
|-----------------------------------------------------|----------------------------------|-------------------------------|---------------------------|---------------------------|
| Subject group type                                  | Reporting group                  | Reporting group               | Reporting group           | Reporting group           |
| Number of subjects analysed                         | 8 <sup>[10]</sup>                | 10 <sup>[11]</sup>            | 8 <sup>[12]</sup>         | 4 <sup>[13]</sup>         |
| Units: ug/mL                                        |                                  |                               |                           |                           |
| geometric mean (geometric coefficient of variation) |                                  |                               |                           |                           |

|                                      |               |               |              |               |
|--------------------------------------|---------------|---------------|--------------|---------------|
| Total Antibody                       | 28.5 (± 14.0) | 39.8 (± 24.5) | 9.3 (± 21.3) | 14.5 (± 22.3) |
| Active Antibody-Drug Conjugate (ADC) | 27.0 (± 18.6) | 40.0 (± 26.3) | 8.8 (± 20.3) | 13.6 (± 31.0) |
| Unconjugated Tubulysin               | 0.4 (± 70.9)  | 0.4 (± 52.3)  | 0.1 (± 36.0) | 0.4 (± 75.0)  |

Notes:

[10] - Total antibody and ADC = 7 participants analyzed

[11] - Unconjugated Tubulysin = 9 participants analyzed

[12] - Unconjugated Tubulysin = 2 participants analyzed

[13] - Unconjugated Tubulysin = 2 participants analyzed

| End point values                                    | BMS 1.2MG/KG<br>Q3W Ex | BMS 0.8MG/KG<br>Q3W+Nivolumab<br>Es | BMS 0.8MG/KG<br>Q3W+Nivolumab<br>Ex |  |
|-----------------------------------------------------|------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type                                  | Subject analysis set   | Subject analysis set                | Subject analysis set                |  |
| Number of subjects analysed                         | 49 <sup>[14]</sup>     | 11 <sup>[15]</sup>                  | 17 <sup>[16]</sup>                  |  |
| Units: ug/mL                                        |                        |                                     |                                     |  |
| geometric mean (geometric coefficient of variation) |                        |                                     |                                     |  |
| Total Antibody                                      | 28.3 (± 22.5)          | 16.7 (± 19.7)                       | 18.8 (± 22.4)                       |  |
| Active Antibody-Drug Conjugate (ADC)                | 27.5 (± 22.6)          | 15.3 (± 27.6)                       | 17.8 (± 24.6)                       |  |
| Unconjugated Tubulysin                              | 0.3 (± 58.2)           | 0.2 (± 42.5)                        | 0.2 (± 42.5)                        |  |

Notes:

[14] - Unconjugated Tubulysin = 45 participants analyzed

[15] - Unconjugated Tubulysin = 5 participants analyzed

[16] - Unconjugated Tubulysin = 11 participants analyzed

## Statistical analyses

No statistical analyses for this end point

## Secondary: Time of Maximum Observed Serum Concentration (Tmax)

|                 |                                                                     |
|-----------------|---------------------------------------------------------------------|
| End point title | Time of Maximum Observed Serum Concentration (Tmax) <sup>[17]</sup> |
|-----------------|---------------------------------------------------------------------|

End point description:

Time of maximum observed serum concentration (Tmax) of BMS-986148 grouped by dose + dose regimen.

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

End point timeframe:

PK blood assessed on cycle 1, day 1

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: Baseline period arm is reported within the subject analysis set

| End point values                     | BMS-986148<br>0.1MG/KG<br>Q3W | BMS-986148<br>0.2MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG<br>Q3W | BMS-986148<br>0.8MG/KG<br>Q3W |
|--------------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Subject group type                   | Reporting group               | Reporting group               | Reporting group               | Reporting group               |
| Number of subjects analysed          | 2 <sup>[18]</sup>             | 2 <sup>[19]</sup>             | 3 <sup>[20]</sup>             | 8 <sup>[21]</sup>             |
| Units: Hours                         |                               |                               |                               |                               |
| median (full range (min-max))        |                               |                               |                               |                               |
| Total Antibody                       | 2.2 (0.3 to 4.0)              | 2.2 (0.3 to 4.1)              | 3.9 (0.5 to 4.7)              | 4.0 (0.2 to 4.8)              |
| Active Antibody-Drug Conjugate (ADC) | 0.2 (0.1 to 0.3)              | 2.2 (0.3 to 4.1)              | 0.5 (0.1 to 3.9)              | 2.5 (0.2 to 4.0)              |
| Unconjugated Tubulysin               | 99999 (99999 to 99999)        | 99999 (99999 to 99999)        | 25.5 (25.5 to 25.5)           | 120.2 (71.8 to 169.7)         |

Notes:

- [18] - Unconjugated Tubulysin = 0 participants analyzed  
 [19] - Unconjugated Tubulysin = 0 participants analyzed  
 [20] - Unconjugated Tubulysin = 1 participants analyzed  
 [21] - Unconjugated Tubulysin = 4 participants analyzed

| End point values                     | BMS-986148<br>1.2MG/KG<br>Q3W Es | BMS-986148<br>1.6MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG QW | BMS-986148<br>0.6MG/KG QW |
|--------------------------------------|----------------------------------|-------------------------------|---------------------------|---------------------------|
| Subject group type                   | Reporting group                  | Reporting group               | Reporting group           | Reporting group           |
| Number of subjects analysed          | 8 <sup>[22]</sup>                | 10 <sup>[23]</sup>            | 8 <sup>[24]</sup>         | 4 <sup>[25]</sup>         |
| Units: Hours                         |                                  |                               |                           |                           |
| median (full range (min-max))        |                                  |                               |                           |                           |
| Total Antibody                       | 4.1 (1.1 to 4.1)                 | 3.9 (0.9 to 4.3)              | 4.0 (0.6 to 4.1)          | 3.8 (1.1 to 3.9)          |
| Active Antibody-Drug Conjugate (ADC) | 3.8 (1.0 to 4.1)                 | 1.5 (0.8 to 4.3)              | 4.0 (0.6 to 4.1)          | 3.8 (1.1 to 3.9)          |
| Unconjugated Tubulysin               | 168.8 (48.0 to 335.5)            | 167.3 (71.4 to 170.0)         | 168.2 (166.9 to 169.4)    | 166.7 (94.7 to 238.7)     |

Notes:

- [22] - Total antibody and ADC = 7 participants analyzed  
 [23] - Unconjugated Tubulysin = 9 participants analyzed  
 [24] - Unconjugated Tubulysin = 2 participants analyzed  
 [25] - Unconjugated Tubulysin = 2 participants analyzed

| End point values                     | BMS 1.2MG/KG<br>Q3W Ex | BMS 0.8MG/KG<br>Q3W+Nivolumab Es | BMS 0.8MG/KG<br>Q3W+Nivolumab Ex |  |
|--------------------------------------|------------------------|----------------------------------|----------------------------------|--|
| Subject group type                   | Subject analysis set   | Subject analysis set             | Subject analysis set             |  |
| Number of subjects analysed          | 49 <sup>[26]</sup>     | 11 <sup>[27]</sup>               | 17 <sup>[28]</sup>               |  |
| Units: Hours                         |                        |                                  |                                  |  |
| median (full range (min-max))        |                        |                                  |                                  |  |
| Total Antibody                       | 4.0 (0.8 to 24.1)      | 1.1 (0.6 to 24.1)                | 4.0 (0.9 to 23.8)                |  |
| Active Antibody-Drug Conjugate (ADC) | 3.9 (0.8 to 4.7)       | 1.0 (0.6 to 4.2)                 | 4.0 (0.9 to 4.0)                 |  |
| Unconjugated Tubulysin               | 166.1 (24.3 to 338.8)  | 165.1 (48.0 to 170.9)            | 166.5 (47.8 to 335.9)            |  |

Notes:

- [26] - Unconjugated Tubulysin = 45 participants analyzed  
 [27] - Unconjugated Tubulysin = 5 participants analyzed  
 [28] - Unconjugated Tubulysin = 11 participants analyzed

## Statistical analyses

No statistical analyses for this end point

## Secondary: Concentration at the End of a Dosing Interval (Ctau)

|                                                                                                                                                                                                                 |                                                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| End point title                                                                                                                                                                                                 | Concentration at the End of a Dosing Interval (Ctau) <sup>[29]</sup> |
| End point description:<br>Concentration at the end of a dosing interval (Ctau) of BMS-986148 grouped by dose + dose regimen.<br>Note: The geometric CV was not calculated. Arithmetic % CV is reported instead. |                                                                      |
| End point type                                                                                                                                                                                                  | Secondary                                                            |
| End point timeframe:<br>PK blood assessed on cycle 1, day 1                                                                                                                                                     |                                                                      |

Notes:

[29] - 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: Baseline period arm is reported within the subject analysis set

| End point values                                    | BMS-986148<br>0.1MG/KG<br>Q3W | BMS-986148<br>0.2MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG<br>Q3W | BMS-986148<br>0.8MG/KG<br>Q3W |
|-----------------------------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Subject group type                                  | Reporting group               | Reporting group               | Reporting group               | Reporting group               |
| Number of subjects analysed                         | 2 <sup>[30]</sup>             | 2 <sup>[31]</sup>             | 2 <sup>[32]</sup>             | 8 <sup>[33]</sup>             |
| Units: ug/mL                                        |                               |                               |                               |                               |
| geometric mean (geometric coefficient of variation) |                               |                               |                               |                               |
| Total Antibody                                      | 0.0035 (± 112.0)              | 0.0333 (± 115.7)              | 0.8233 (± 131.8)              | 0.4426 (± 106.1)              |
| Active Antibody-Drug Conjugate (ADC)                | 0.0633 (± 141.3)              | 99999 (± 99999)               | 0.0058 (± 99999)              | 0.0309 (± 123.8)              |
| Unconjugated Tubulysin                              | 99999 (± 99999)               | 99999 (± 99999)               | 99999 (± 99999)               | 99999 (± 99999)               |

Notes:

[30] - Unconjugated Tubulysin = 0 participants analyzed

[31] - Unconjugated Tubulysin and ADC = 0 participants analyzed

[32] - ADC = 1 participant analyzed Unconjugated Tubulysin = 0 participants analyzed

[33] - Unconjugated Tubulysin = 0 participants analyzed

| End point values                                    | BMS-986148<br>1.2MG/KG<br>Q3W Es | BMS-986148<br>1.6MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG QW | BMS-986148<br>0.6MG/KG QW |
|-----------------------------------------------------|----------------------------------|-------------------------------|---------------------------|---------------------------|
| Subject group type                                  | Reporting group                  | Reporting group               | Reporting group           | Reporting group           |
| Number of subjects analysed                         | 7 <sup>[34]</sup>                | 10 <sup>[35]</sup>            | 8 <sup>[36]</sup>         | 3 <sup>[37]</sup>         |
| Units: ug/mL                                        |                                  |                               |                           |                           |
| geometric mean (geometric coefficient of variation) |                                  |                               |                           |                           |
| Total Antibody                                      | 1.0917 (± 91.9)                  | 1.4101 (± 101.8)              | 3.2035 (± 20.2)           | 3.8872 (± 46.1)           |
| Active Antibody-Drug Conjugate (ADC)                | 0.2121 (± 111.3)                 | 0.3049 (± 110.0)              | 1.2705 (± 39.5)           | 1.9068 (± 59.1)           |
| Unconjugated Tubulysin                              | 0.2590 (± 77.1)                  | 0.1630 (± 0.9)                | 0.1388 (± 36.0)           | 0.3539 (± 75.0)           |

Notes:

[34] - Unconjugated Tubulysin = 3 participants analyzed

[35] - Total antibody - 8 participants analyzed Unconjugated Tubulysin = 2 participants analyzed

[36] - Unconjugated Tubulysin = 2 participants analyzed

[37] - Unconjugated Tubulysin = 2 participants analyzed

| End point values                                    | BMS 1.2MG/KG<br>Q3W Ex | BMS 0.8MG/KG<br>Q3W+Nivolumab<br>Es | BMS 0.8MG/KG<br>Q3W+Nivolumab<br>Ex |  |
|-----------------------------------------------------|------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type                                  | Subject analysis set   | Subject analysis set                | Subject analysis set                |  |
| Number of subjects analysed                         | 46 <sup>[38]</sup>     | 10 <sup>[39]</sup>                  | 17 <sup>[40]</sup>                  |  |
| Units: ug/mL                                        |                        |                                     |                                     |  |
| geometric mean (geometric coefficient of variation) |                        |                                     |                                     |  |
| Total Antibody                                      | 1.1938 (± 98.7)        | 0.2133 (± 114.0)                    | 0.7544 (± 83.5)                     |  |
| Active Antibody-Drug Conjugate (ADC)                | 0.1558 (± 123.4)       | 0.1119 (± 187.1)                    | 0.0797 (± 103.7)                    |  |

|                        |                      |                      |                       |  |
|------------------------|----------------------|----------------------|-----------------------|--|
| Unconjugated Tubulysin | 0.1634 ( $\pm$ 48.2) | 99999 ( $\pm$ 99999) | 0.1330 ( $\pm$ 99999) |  |
|------------------------|----------------------|----------------------|-----------------------|--|

Notes:

[38] - Unconjugated Tubulysin = 6 participants analyzed

[39] - Total antibody = 9 participants analyzed Unconjugated Tubulysin = 0 participants analyzed

[40] - Unconjugated Tubulysin = 1 participant analyzed

## Statistical analyses

No statistical analyses for this end point

## Secondary: Trough Observed Serum Concentration (Ctough)

|                 |                                                              |
|-----------------|--------------------------------------------------------------|
| End point title | Trough Observed Serum Concentration (Ctough) <sup>[41]</sup> |
|-----------------|--------------------------------------------------------------|

End point description:

Trough observed serum concentration (Ctough) of BMS-986148 grouped by dose + dose regimen.

Note: The geometric CV was not calculated. Arithmetic % CV is reported instead.

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

End point timeframe:

PK blood assessment include cycle 2-day 1 and cycle 1-day 8

Notes:

[41] - 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: Baseline period arm is reported within the subject analysis set

| End point values                                    | BMS-986148<br>0.1MG/KG<br>Q3W | BMS-986148<br>0.2MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG<br>Q3W | BMS-986148<br>0.8MG/KG<br>Q3W |
|-----------------------------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Subject group type                                  | Reporting group               | Reporting group               | Reporting group               | Reporting group               |
| Number of subjects analysed                         | 2                             | 2                             | 3                             | 7                             |
| Units: ug/mL                                        |                               |                               |                               |                               |
| geometric mean (geometric coefficient of variation) |                               |                               |                               |                               |
| Total Antibody                                      | 0.1 ( $\pm$ 0.0)              | 0.1 ( $\pm$ 0.00)             | 0.1 ( $\pm$ 0.00)             | 0.79676 ( $\pm$ 92.4)         |
| Active Antibody-Drug Conjugate (ADC)                | 0.1 ( $\pm$ 0.0)              | 0.1 ( $\pm$ 0.00)             | 0.1 ( $\pm$ 0.00)             | 0.27671 ( $\pm$ 95.3)         |
| Unconjugated Tubulysin                              | 0.0005 ( $\pm$ 0.0)           | 0.0005 ( $\pm$ 0.0)           | 0.0005 ( $\pm$ 0.0)           | 0.0005 ( $\pm$ 0.0)           |

| End point values                                    | BMS-986148<br>1.2MG/KG<br>Q3W Es | BMS-986148<br>1.6MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG QW | BMS-986148<br>0.6MG/KG QW |
|-----------------------------------------------------|----------------------------------|-------------------------------|---------------------------|---------------------------|
| Subject group type                                  | Reporting group                  | Reporting group               | Reporting group           | Reporting group           |
| Number of subjects analysed                         | 8                                | 6                             | 8                         | 3                         |
| Units: ug/mL                                        |                                  |                               |                           |                           |
| geometric mean (geometric coefficient of variation) |                                  |                               |                           |                           |
| Total Antibody                                      | 1.23291 ( $\pm$ 81.7)            | 0.92146 ( $\pm$ 125.9)        | 3.20352 ( $\pm$ 20.2)     | 3.88717 ( $\pm$ 46.1)     |
| Active Antibody-Drug Conjugate (ADC)                | 0.36894 ( $\pm$ 90.7)            | 0.21835 ( $\pm$ 152.7)        | 1.27047 ( $\pm$ 39.5)     | 1.90678 ( $\pm$ 59.1)     |
| Unconjugated Tubulysin                              | 0.0009 ( $\pm$ 127.6)            | 0.0007 ( $\pm$ 66.6)          | 0.0006 ( $\pm$ 64.7)      | 0.00018 ( $\pm$ 104.0)    |

| End point values                                    | BMS 1.2MG/KG<br>Q3W Ex | BMS 0.8MG/KG<br>Q3W+Nivolumab Es | BMS 0.8MG/KG<br>Q3W+Nivolumab Ex |  |
|-----------------------------------------------------|------------------------|----------------------------------|----------------------------------|--|
| Subject group type                                  | Subject analysis set   | Subject analysis set             | Subject analysis set             |  |
| Number of subjects analysed                         | 39                     | 10                               | 13                               |  |
| Units: ug/mL                                        |                        |                                  |                                  |  |
| geometric mean (geometric coefficient of variation) |                        |                                  |                                  |  |
| Total Antibody                                      | 1.14568 (± 104.4)      | 0.33875 (± 122.1)                | 0.77912 (± 79.1)                 |  |
| Active Antibody-Drug Conjugate (ADC)                | 0.31524 (± 111.4)      | 0.18096 (± 97.4)                 | 0.24389 (± 81.0)                 |  |
| Unconjugated Tubulysin                              | 0.0006 (± 80.7)        | 0.0005 (± 0.0)                   | 0.0005 (± 40.8)                  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Area Under the Concentration-Time Curve from Time Zero to Time T (AUC(0-t))

|                 |                                                                                             |
|-----------------|---------------------------------------------------------------------------------------------|
| End point title | Area Under the Concentration-Time Curve from Time Zero to Time T (AUC(0-t)) <sup>[42]</sup> |
|-----------------|---------------------------------------------------------------------------------------------|

End point description:

Area under the concentration-time curve from time Zero to time T (AUC(0-t)) of BMS-986148 grouped by dose + dose regimen. Note: The geometric CV was not calculated. Arithmetic % CV is reported instead.

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

End point timeframe:

PK blood assessment include cycle 1-day 1

Notes:

[42] - 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: Baseline period arm is reported within the subject analysis set

| End point values                                    | BMS-986148<br>0.1MG/KG<br>Q3W | BMS-986148<br>0.2MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG<br>Q3W | BMS-986148<br>0.8MG/KG<br>Q3W |
|-----------------------------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Subject group type                                  | Reporting group               | Reporting group               | Reporting group               | Reporting group               |
| Number of subjects analysed                         | 2 <sup>[43]</sup>             | 2 <sup>[44]</sup>             | 3 <sup>[45]</sup>             | 8 <sup>[46]</sup>             |
| Units: h*ug/mL                                      |                               |                               |                               |                               |
| geometric mean (geometric coefficient of variation) |                               |                               |                               |                               |
| Total Antibody                                      | 152.6 (± 31.6)                | 232.5 (± 17.5)                | 129.6 (± 131.3)               | 1979.5 (± 69.6)               |
| Active Antibody-Drug Conjugate (ADC)                | 88.6 (± 48.7)                 | 70.7 (± 42.9)                 | 60.8 (± 136.2)                | 1042.1 (± 68.6)               |
| Unconjugated Tubulysin                              | 99999 (± 99999)               | 99999 (± 99999)               | 49.6 (± 99999)                | 29.6 (± 42.8)                 |

Notes:

[43] - Unconjugated Tubulysin = 0 participants analyzed

[44] - Unconjugated Tubulysin = 0 participants analyzed

[45] - Unconjugated Tubulysin = 1 participants analyzed

[46] - Unconjugated Tubulysin = 4 participants analyzed

| End point values                                    | BMS-986148<br>1.2MG/KG<br>Q3W Es | BMS-986148<br>1.6MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG QW | BMS-986148<br>0.6MG/KG QW |
|-----------------------------------------------------|----------------------------------|-------------------------------|---------------------------|---------------------------|
| Subject group type                                  | Reporting group                  | Reporting group               | Reporting group           | Reporting group           |
| Number of subjects analysed                         | 8 <sup>[47]</sup>                | 10 <sup>[48]</sup>            | 8 <sup>[49]</sup>         | 4 <sup>[50]</sup>         |
| Units: h*ug/mL                                      |                                  |                               |                           |                           |
| geometric mean (geometric coefficient of variation) |                                  |                               |                           |                           |
| Total Antibody                                      | 4285.7 (± 29.3)                  | 5399.8 (± 40.1)               | 858.0 (± 22.9)            | 1278.8 (± 35.1)           |
| Active Antibody-Drug Conjugate (ADC)                | 2493.1 (± 25.1)                  | 3083.6 (± 32.3)               | 565.4 (± 30.3)            | 927.3 (± 38.7)            |
| Unconjugated Tubulysin                              | 197.0 (± 59.4)                   | 80.1 (± 73.4)                 | 9.3 (± 73.0)              | 42.5 (± 84.3)             |

Notes:

[47] - Total antibody and ADC = 7 participants analyzed

[48] - Unconjugated Tubulysin = 9 participants analyzed

[49] - Unconjugated Tubulysin = 2 participants analyzed

[50] - Unconjugated Tubulysin = 2 participants analyzed

| End point values                                    | BMS-986148<br>0.8MG/KG<br>Q3W+Nivolumab | BMS 1.2MG/KG<br>Q3W Ex |  |  |
|-----------------------------------------------------|-----------------------------------------|------------------------|--|--|
| Subject group type                                  | Reporting group                         | Subject analysis set   |  |  |
| Number of subjects analysed                         | 11 <sup>[51]</sup>                      | 49 <sup>[52]</sup>     |  |  |
| Units: h*ug/mL                                      |                                         |                        |  |  |
| geometric mean (geometric coefficient of variation) |                                         |                        |  |  |
| Total Antibody                                      | 1815.8 (± 43.4)                         | 3472.6 (± 47.1)        |  |  |
| Active Antibody-Drug Conjugate (ADC)                | 1059.0 (± 44.8)                         | 1984.7 (± 45.7)        |  |  |
| Unconjugated Tubulysin                              | 25.5 (± 58.8)                           | 42.3 (± 80.4)          |  |  |

Notes:

[51] - Unconjugated Tubulysin = 5 participants analyzed

[52] - Unconjugated Tubulysin = 45 participants analyzed

## Statistical analyses

No statistical analyses for this end point

## Secondary: Area Under the Concentration-Time Curve in One Dosing Interval (AUC[TAU])

|                        |                                                                                                                                                                                                       |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title        | Area Under the Concentration-Time Curve in One Dosing Interval (AUC[TAU]) <sup>[53]</sup>                                                                                                             |
| End point description: | Area under the concentration-time curve in one dosing interval (AUC[TAU]) of BMS-986148 grouped by dose + dose regimen Note: The geometric CV was not calculated. Arithmetic % CV is reported instead |
| End point type         | Secondary                                                                                                                                                                                             |

End point timeframe:

PK blood assessment include cycle 1-day 1

Notes:

[53] - 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: Baseline period arm is reported within the subject analysis set

| End point values                                    | BMS-986148<br>0.1MG/KG<br>Q3W | BMS-986148<br>0.2MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG<br>Q3W | BMS-986148<br>0.8MG/KG<br>Q3W |
|-----------------------------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Subject group type                                  | Reporting group               | Reporting group               | Reporting group               | Reporting group               |
| Number of subjects analysed                         | 2 <sup>[54]</sup>             | 2 <sup>[55]</sup>             | 2 <sup>[56]</sup>             | 8 <sup>[57]</sup>             |
| Units: h*ug/mL                                      |                               |                               |                               |                               |
| geometric mean (geometric coefficient of variation) |                               |                               |                               |                               |
| Total Antibody                                      | 179.3 (± 34.8)                | 265.7 (± 13.3)                | 344.6 (± 98.5)                | 2059.3 (± 68.7)               |
| Active Antibody-Drug Conjugate (ADC)                | 109.0 (± 35.2)                | 99999 (± 99999)               | 371.6 (± 99999)               | 1098.7 (± 67.5)               |
| Unconjugated Tubulysin                              | 99999 (± 99999)               | 99999 (± 99999)               | 99999 (± 99999)               | 99999 (± 99999)               |

Notes:

[54] - Unconjugated Tubulysin = 0 participants analyzed

[55] - ADC and Unconjugated Tubulysin = 0 participants analyzed

[56] - ADC = 1 participants analyzed Unconjugated Tubulysin = 0 participants analyzed

[57] - Unconjugated Tubulysin = 0 participants analyzed

| End point values                                    | BMS-986148<br>1.2MG/KG<br>Q3W Es | BMS-986148<br>1.6MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG QW | BMS-986148<br>0.6MG/KG QW |
|-----------------------------------------------------|----------------------------------|-------------------------------|---------------------------|---------------------------|
| Subject group type                                  | Reporting group                  | Reporting group               | Reporting group           | Reporting group           |
| Number of subjects analysed                         | 7 <sup>[58]</sup>                | 10 <sup>[59]</sup>            | 8 <sup>[60]</sup>         | 3 <sup>[61]</sup>         |
| Units: h*ug/mL                                      |                                  |                               |                           |                           |
| geometric mean (geometric coefficient of variation) |                                  |                               |                           |                           |
| Total Antibody                                      | 4316.1 (± 28.8)                  | 5318.6 (± 36.9)               | 858.0 (± 22.9)            | 1533.5 (± 19.2)           |
| Active Antibody-Drug Conjugate (ADC)                | 2507.2 (± 24.7)                  | 3246.0 (± 36.6)               | 565.4 (± 30.3)            | 1063.9 (± 32.2)           |
| Unconjugated Tubulysin                              | 197.0 (± 59.4)                   | 173.4 (± 48.2)                | 9.3 (± 73.0)              | 42.5 (± 84.3)             |

Notes:

[58] - Unconjugated Tubulysin = 3 participants analyzed

[59] - Total Antibody = 8 participants analyzed Unconjugated Tubulysin = 2 participants analyzed

[60] - Unconjugated Tubulysin = 2 participants analyzed

[61] - Unconjugated Tubulysin = 2 participants analyzed

| End point values                                    | BMS 1.2MG/KG<br>Q3W Ex | BMS 0.8MG/KG<br>Q3W+Nivolumab<br>Es | BMS 0.8MG/KG<br>Q3W+Nivolumab<br>Ex |  |
|-----------------------------------------------------|------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type                                  | Subject analysis set   | Subject analysis set                | Subject analysis set                |  |
| Number of subjects analysed                         | 46 <sup>[62]</sup>     | 10 <sup>[63]</sup>                  | 17 <sup>[64]</sup>                  |  |
| Units: h*ug/mL                                      |                        |                                     |                                     |  |
| geometric mean (geometric coefficient of variation) |                        |                                     |                                     |  |
| Total Antibody                                      | 4159.4 (± 39.5)        | 1839.0 (± 45.4)                     | 2689.9 (± 34.0)                     |  |

|                                      |                      |                      |                      |  |
|--------------------------------------|----------------------|----------------------|----------------------|--|
| Active Antibody-Drug Conjugate (ADC) | 2271.7 ( $\pm$ 40.1) | 1094.9 ( $\pm$ 48.0) | 1478.1 ( $\pm$ 36.6) |  |
| Unconjugated Tubulysin               | 148.9 ( $\pm$ 30.3)  | 99999 ( $\pm$ 99999) | 102.4 ( $\pm$ 99999) |  |

Notes:

[62] - Unconjugated Tubulysin = 6 participants analyzed

[63] - Total antibody = 9 participants analyzed Unconjugated Tubulysin = 0 participants analyzed

[64] - Unconjugated Tubulysin = 1 participants analyzed

## Statistical analyses

No statistical analyses for this end point

## Secondary: Best Overall Response (BOR)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Best Overall Response (BOR) |
| End point description:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                             |
| Best overall response is defined as the best response designation over the study as a whole, recorded between the dates of first dose until the last tumor assessment prior to subsequent therapy. Participants are grouped by cohorts (Mesothelioma, Pancreatic, Ovarian, Non-small Cell Lung Cancer (NSCLC), and Gastric). Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to < 10 mm. Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study. The sum must also demonstrate an absolute increase of at least 5 mm. Stable Disease (SD): Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum diameters while on study. |                             |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Secondary                   |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                             |
| Up to 58 months                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                             |

| End point values            | BMS-986148 Mesothelioma | BMS-986148+Nivolumab Mesothelioma | BMS-986148 Ovarian   | BMS-986148+Nivolumab Ovarian |
|-----------------------------|-------------------------|-----------------------------------|----------------------|------------------------------|
| Subject group type          | Subject analysis set    | Subject analysis set              | Subject analysis set | Subject analysis set         |
| Number of subjects analysed | 25                      | 13                                | 22                   | 2                            |
| Units: Participants         |                         |                                   |                      |                              |
| Complete Response (CR)      | 0                       | 0                                 | 0                    | 0                            |
| Partial Response (PR)       | 1                       | 3                                 | 2                    | 0                            |
| Stable Disease (SD)         | 13                      | 8                                 | 11                   | 2                            |
| Progressive Disease (PD)    | 7                       | 1                                 | 7                    | 0                            |

| End point values            | BMS-986148 Pancreatic | BMS-986148+Nivolumab Pancreatic | BMS-986148 NSCLC     | BMS-986148+Nivolumab NSCLC |
|-----------------------------|-----------------------|---------------------------------|----------------------|----------------------------|
| Subject group type          | Subject analysis set  | Subject analysis set            | Subject analysis set | Subject analysis set       |
| Number of subjects analysed | 18                    | 6                               | 4                    | 2                          |
| Units: Participants         |                       |                                 |                      |                            |
| Complete Response (CR)      | 0                     | 0                               | 0                    | 0                          |
| Partial Response (PR)       | 0                     | 0                               | 0                    | 0                          |
| Stable Disease (SD)         | 4                     | 1                               | 1                    | 1                          |

|                          |    |   |   |   |
|--------------------------|----|---|---|---|
| Progressive Disease (PD) | 11 | 2 | 2 | 1 |
|--------------------------|----|---|---|---|

| End point values            | BMS-986148<br>Gastric | BMS-<br>986148+Nivolu<br>mab Gastric |  |  |
|-----------------------------|-----------------------|--------------------------------------|--|--|
| Subject group type          | Subject analysis set  | Subject analysis set                 |  |  |
| Number of subjects analysed | 3                     | 1                                    |  |  |
| Units: Participants         |                       |                                      |  |  |
| Complete Response (CR)      | 0                     | 0                                    |  |  |
| Partial Response (PR)       | 0                     | 0                                    |  |  |
| Stable Disease (SD)         | 1                     | 0                                    |  |  |
| Progressive Disease (PD)    | 2                     | 1                                    |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Objective Response Rate (ORR)

|                 |                               |
|-----------------|-------------------------------|
| End point title | Objective Response Rate (ORR) |
|-----------------|-------------------------------|

End point description:

Objective response rate is defined as the total percentage of participants whose best overall response (BOR) is either a complete response or partial response divided by the total percentage of participants who are grouped by cohorts (Mesothelioma, Pancreatic, Ovarian, Non-small Cell Lung (NSCL), and Gastric). Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to < 10 mm. Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

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

End point timeframe:

Up to 58 months

| End point values                  | BMS-986148<br>Mesothelioma | BMS-<br>986148+Nivolu<br>mab<br>Mesothelioma | BMS-986148<br>Ovarian | BMS-<br>986148+Nivolu<br>mab Ovarian |
|-----------------------------------|----------------------------|----------------------------------------------|-----------------------|--------------------------------------|
| Subject group type                | Subject analysis set       | Subject analysis set                         | Subject analysis set  | Subject analysis set                 |
| Number of subjects analysed       | 25                         | 13                                           | 22                    | 29                                   |
| Units: Percentage of participants |                            |                                              |                       |                                      |
| number (confidence interval 95%)  | 1 (0.1 to 20.4)            | 3 (3.0 to 53.8)                              | 2 (1.1 to 29.2)       | 2 (0.8 to 22.8)                      |

| End point values                  | BMS-986148<br>Pancreatic | BMS-<br>986148+Nivolu<br>mab Pancreatic | BMS-986148<br>NSCLC  | BMS-<br>986148+Nivolu<br>mab NSCLC |
|-----------------------------------|--------------------------|-----------------------------------------|----------------------|------------------------------------|
| Subject group type                | Subject analysis set     | Subject analysis set                    | Subject analysis set | Subject analysis set               |
| Number of subjects analysed       | 18                       | 6                                       | 4                    | 2                                  |
| Units: Percentage of participants |                          |                                         |                      |                                    |

|                                  |                        |                        |                        |                        |
|----------------------------------|------------------------|------------------------|------------------------|------------------------|
| number (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
|----------------------------------|------------------------|------------------------|------------------------|------------------------|

| End point values                  | BMS-986148 Gastric     | BMS-986148+Nivolumab Gastric |  |  |
|-----------------------------------|------------------------|------------------------------|--|--|
| Subject group type                | Subject analysis set   | Subject analysis set         |  |  |
| Number of subjects analysed       | 3                      | 1                            |  |  |
| Units: Percentage of participants |                        |                              |  |  |
| number (confidence interval 95%)  | 99999 (99999 to 99999) | 99999 (99999 to 99999)       |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Duration of Response (DoR)

|                                                                                                                                                                                                                                                                                                          |                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| End point title                                                                                                                                                                                                                                                                                          | Duration of Response (DoR) |
| End point description:                                                                                                                                                                                                                                                                                   |                            |
| Duration of response is defined as the time between the date of first response and the subsequent date of objectively documented disease progression or death, whichever occurs first. Participants are grouped by cohorts (Mesothelioma, Pancreatic, Ovarian, Non-small Cell Lung (NSCL), and Gastric). |                            |
| End point type                                                                                                                                                                                                                                                                                           | Secondary                  |
| End point timeframe:                                                                                                                                                                                                                                                                                     |                            |
| Up to 58 months                                                                                                                                                                                                                                                                                          |                            |

| End point values              | BMS-986148 Mesothelioma | BMS-986148+Nivolumab Mesothelioma | BMS-986148 Ovarian   | BMS-986148+Nivolumab Ovarian |
|-------------------------------|-------------------------|-----------------------------------|----------------------|------------------------------|
| Subject group type            | Subject analysis set    | Subject analysis set              | Subject analysis set | Subject analysis set         |
| Number of subjects analysed   | 25                      | 13                                | 22                   | 0 <sup>[65]</sup>            |
| Units: Months                 |                         |                                   |                      |                              |
| median (full range (min-max)) | 29.7 (29.7 to 29.7)     | 8.97 (5.1 to 13.3)                | 99999 (3.0 to 99999) | ( to )                       |

Notes:

[65] - 0 subjects analyzed

| End point values              | BMS-986148 Pancreatic | BMS-986148+Nivolumab Pancreatic | BMS-986148 NSCLC       | BMS-986148+Nivolumab NSCLC |
|-------------------------------|-----------------------|---------------------------------|------------------------|----------------------------|
| Subject group type            | Subject analysis set  | Subject analysis set            | Subject analysis set   | Subject analysis set       |
| Number of subjects analysed   | 0 <sup>[66]</sup>     | 6                               | 4                      | 0 <sup>[67]</sup>          |
| Units: Months                 |                       |                                 |                        |                            |
| median (full range (min-max)) | ( to )                | 99999 (99999 to 99999)          | 99999 (99999 to 99999) | ( to )                     |

Notes:

[66] - 0 subjects analyzed

[67] - 0 subjects analyzed

| End point values              | BMS-986148<br>Gastric | BMS-<br>986148+Nivolu<br>mab Gastric |  |  |
|-------------------------------|-----------------------|--------------------------------------|--|--|
| Subject group type            | Subject analysis set  | Subject analysis set                 |  |  |
| Number of subjects analysed   | 0 <sup>[68]</sup>     | 0 <sup>[69]</sup>                    |  |  |
| Units: Months                 |                       |                                      |  |  |
| median (full range (min-max)) | ( to )                | ( to )                               |  |  |

Notes:

[68] - 0 subjects analyzed

[69] - 0 subjects analyzed

## Statistical analyses

No statistical analyses for this end point

## Secondary: Progression Free Survival (PFS)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Progression Free Survival (PFS) |
| End point description:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                 |
| Progression Free Survival is defined as the time from the first dose of study medication to the date of the first objective documentation of tumor progression or death due to any cause. Progression is defined with at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study and the sum must also demonstrate an absolute increase of at least 5 mm. Participants who did not progress nor died will be censored on the date of their last tumor assessment. Participants are grouped by cohorts (Mesothelioma, Pancreatic, Ovarian, Non-small Cell Lung (NSCL), and Gastric). |                                 |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Secondary                       |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                 |
| Up to 58 months                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                 |

| End point values                 | BMS-986148<br>Mesothelioma | BMS-<br>986148+Nivolu<br>mab<br>Mesothelioma | BMS-986148<br>Ovarian | BMS-<br>986148+Nivolu<br>mab Ovarian |
|----------------------------------|----------------------------|----------------------------------------------|-----------------------|--------------------------------------|
| Subject group type               | Subject analysis set       | Subject analysis set                         | Subject analysis set  | Subject analysis set                 |
| Number of subjects analysed      | 25                         | 13                                           | 22                    | 0 <sup>[70]</sup>                    |
| Units: Months                    |                            |                                              |                       |                                      |
| median (confidence interval 95%) | 2.56 (1.41 to 4.01)        | 5.19 (2.56 to 12.06)                         | 2.79 (1.28 to 4.17)   | ( to )                               |

Notes:

[70] - 0 subjects analyzed

| End point values                 | BMS-986148<br>Pancreatic | BMS-<br>986148+Nivolu<br>mab Pancreatic | BMS-986148<br>NSCLC  | BMS-<br>986148+Nivolu<br>mab NSCLC |
|----------------------------------|--------------------------|-----------------------------------------|----------------------|------------------------------------|
| Subject group type               | Subject analysis set     | Subject analysis set                    | Subject analysis set | Subject analysis set               |
| Number of subjects analysed      | 0 <sup>[71]</sup>        | 6                                       | 4                    | 0 <sup>[72]</sup>                  |
| Units: Months                    |                          |                                         |                      |                                    |
| median (confidence interval 95%) | ( to )                   | 1.66 (1.22 to 2.14)                     | 1.49 (1.15 to 5.65)  | ( to )                             |

Notes:

[71] - 0 subjects analyzed

[72] - 0 subjects analyzed

| End point values                 | BMS-986148<br>Gastric | BMS-<br>986148+Nivolu<br>mab Gastric |  |  |
|----------------------------------|-----------------------|--------------------------------------|--|--|
| Subject group type               | Subject analysis set  | Subject analysis set                 |  |  |
| Number of subjects analysed      | 0 <sup>[73]</sup>     | 0 <sup>[74]</sup>                    |  |  |
| Units: Months                    |                       |                                      |  |  |
| median (confidence interval 95%) | ( to )                | ( to )                               |  |  |

Notes:

[73] - 0 subjects analyzed

[74] - 0 subjects analyzed

## Statistical analyses

No statistical analyses for this end point

## Secondary: Progression Free Survival Rate (PFSR) at Week t

|                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                               | Progression Free Survival Rate (PFSR) at Week t |
| End point description:<br>Progression free survival rate is defined as the percentage of participants who remain progression free and surviving at 't' weeks (t=4-12 months). The percentage will be calculated by the product-limit method (Kaplan-Meier estimate) which takes into account censored data. Participants are grouped by cohorts (Mesothelioma, Pancreatic, Ovarian, Non-small Cell Lung (NSCL), and Gastric). |                                                 |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                | Secondary                                       |
| End point timeframe:<br>Up to 58 months                                                                                                                                                                                                                                                                                                                                                                                       |                                                 |

| End point values                  | BMS-986148<br>Mesothelioma | BMS-<br>986148+Nivolu<br>mab<br>Mesothelioma | BMS-986148<br>Ovarian  | BMS-<br>986148+Nivolu<br>mab Ovarian |
|-----------------------------------|----------------------------|----------------------------------------------|------------------------|--------------------------------------|
| Subject group type                | Subject analysis set       | Subject analysis set                         | Subject analysis set   | Subject analysis set                 |
| Number of subjects analysed       | 25                         | 13                                           | 22                     | 0 <sup>[75]</sup>                    |
| Units: Percentage of participants |                            |                                              |                        |                                      |
| number (confidence interval 95%)  |                            |                                              |                        |                                      |
| 4 months                          | 0.35 (0.15 to 0.54)        | 0.65 (0.37 to 0.93)                          | 0.40 (0.18 to 0.62)    | ( to )                               |
| 6 months                          | 0.30 (0.11 to 0.49)        | 0.47 (0.17 to 0.76)                          | 99999 (99999 to 99999) | ( to )                               |

Notes:

[75] - 0 subjects analyzed

| End point values                  | BMS-986148<br>Pancreatic | BMS-<br>986148+Nivolu<br>mab Pancreatic | BMS-986148<br>NSCLC  | BMS-<br>986148+Nivolu<br>mab NSCLC |
|-----------------------------------|--------------------------|-----------------------------------------|----------------------|------------------------------------|
| Subject group type                | Subject analysis set     | Subject analysis set                    | Subject analysis set | Subject analysis set               |
| Number of subjects analysed       | 0 <sup>[76]</sup>        | 0 <sup>[77]</sup>                       | 0 <sup>[78]</sup>    | 0 <sup>[79]</sup>                  |
| Units: Percentage of participants |                          |                                         |                      |                                    |
| number (confidence interval 95%)  |                          |                                         |                      |                                    |

|          |        |        |        |        |
|----------|--------|--------|--------|--------|
| 4 months | ( to ) | ( to ) | ( to ) | ( to ) |
| 6 months | ( to ) | ( to ) | ( to ) | ( to ) |

Notes:

[76] - 0 subjects analyzed

[77] - 0 subjects analyzed

[78] - 0 subjects analyzed

[79] - 0 subjects analyzed

| End point values                  | BMS-986148<br>Gastric | BMS-<br>986148+Nivolu<br>mab Gastric |  |  |
|-----------------------------------|-----------------------|--------------------------------------|--|--|
| Subject group type                | Subject analysis set  | Subject analysis set                 |  |  |
| Number of subjects analysed       | 0 <sup>[80]</sup>     | 0 <sup>[81]</sup>                    |  |  |
| Units: Percentage of participants |                       |                                      |  |  |
| number (confidence interval 95%)  |                       |                                      |  |  |
| 4 months                          | ( to )                | ( to )                               |  |  |
| 6 months                          | ( to )                | ( to )                               |  |  |

Notes:

[80] - 0 subjects analyzed

[81] - 0 subjects analyzed

## Statistical analyses

No statistical analyses for this end point

## Secondary: Changes in QT Corrected by the Fridericia Formula (QTcF) from Baseline, at Selected Times

|                 |                                                                                                           |
|-----------------|-----------------------------------------------------------------------------------------------------------|
| End point title | Changes in QT Corrected by the Fridericia Formula (QTcF) from Baseline, at Selected Times <sup>[82]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------|

End point description:

Changes of participants in QT corrected by the fridericia formula (QTcF) Interval from baseline at ≤ 30 msec, >30 - ≤ 60 msec, and > 60 msec grouped by dose + dose regimen

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

End point timeframe:

Up to 58 months

Notes:

[82] - 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: Baseline period arm is reported within the subject analysis set

| End point values            | BMS-986148<br>0.1MG/KG<br>Q3W | BMS-986148<br>0.2MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG<br>Q3W | BMS-986148<br>0.8MG/KG<br>Q3W |
|-----------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Subject group type          | Reporting group               | Reporting group               | Reporting group               | Reporting group               |
| Number of subjects analysed | 2                             | 2                             | 3                             | 8                             |
| Units: Participants         |                               |                               |                               |                               |
| ≤ 30 msec,                  | 1                             | 2                             | 2                             | 6                             |
| >30 - ≤ 60 msec             | 1                             | 0                             | 1                             | 2                             |
| > 60 msec                   | 0                             | 0                             | 0                             | 0                             |

| End point values | BMS-986148 | BMS-986148 | BMS-986148 | BMS-986148 |
|------------------|------------|------------|------------|------------|
|------------------|------------|------------|------------|------------|

|                             | 1.2MG/KG<br>Q3W Es | 1.6MG/KG<br>Q3W | 0.4MG/KG QW     | 0.6MG/KG QW     |
|-----------------------------|--------------------|-----------------|-----------------|-----------------|
| Subject group type          | Reporting group    | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8                  | 10              | 8               | 4               |
| Units: Participants         |                    |                 |                 |                 |
| <= 30 msec,                 | 8                  | 9               | 5               | 3               |
| >30 - <= 60 msec            | 0                  | 1               | 3               | 1               |
| > 60 msec                   | 0                  | 0               | 0               | 0               |

| End point values            | BMS-986148<br>0.8MG/KG<br>Q3W+Nivolumab | BMS 1.2MG/KG<br>Q3W Ex |  |  |
|-----------------------------|-----------------------------------------|------------------------|--|--|
| Subject group type          | Reporting group                         | Subject analysis set   |  |  |
| Number of subjects analysed | 30                                      | 51                     |  |  |
| Units: Participants         |                                         |                        |  |  |
| <= 30 msec,                 | 23                                      | 37                     |  |  |
| >30 - <= 60 msec            | 7                                       | 12                     |  |  |
| > 60 msec                   | 0                                       | 2                      |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Incidence of Participants with Anti-Drug Antibody (ADA)

End point title Incidence of Participants with Anti-Drug Antibody (ADA)<sup>[83]</sup>

End point description:

Incidence of participants with anti-drug antibody (ADA) status grouped by dose + dose regimen

End point type Secondary

End point timeframe:

Up to 58 months

Notes:

[83] - 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: Baseline period arm is reported within the subject analysis set

| End point values            | BMS-986148<br>0.1MG/KG<br>Q3W | BMS-986148<br>0.2MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG<br>Q3W | BMS-986148<br>0.8MG/KG<br>Q3W |
|-----------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Subject group type          | Reporting group               | Reporting group               | Reporting group               | Reporting group               |
| Number of subjects analysed | 0 <sup>[84]</sup>             | 0 <sup>[85]</sup>             | 0 <sup>[86]</sup>             | 0 <sup>[87]</sup>             |
| Units: Participants         |                               |                               |                               |                               |
| ADA positive                |                               |                               |                               |                               |
| ADA negative                |                               |                               |                               |                               |

Notes:

[84] - 0 subjects analyzed

[85] - 0 subjects analyzed

[86] - 0 subjects analyzed

[87] - 0 subjects analyzed

| End point values            | BMS-986148<br>1.2MG/KG<br>Q3W Es | BMS-986148<br>1.6MG/KG<br>Q3W | BMS-986148<br>0.4MG/KG QW | BMS-986148<br>0.6MG/KG QW |
|-----------------------------|----------------------------------|-------------------------------|---------------------------|---------------------------|
| Subject group type          | Reporting group                  | Reporting group               | Reporting group           | Reporting group           |
| Number of subjects analysed | 0 <sup>[88]</sup>                | 0 <sup>[89]</sup>             | 0 <sup>[90]</sup>         | 0 <sup>[91]</sup>         |
| Units: Participants         |                                  |                               |                           |                           |
| ADA positive                |                                  |                               |                           |                           |
| ADA negative                |                                  |                               |                           |                           |

Notes:

[88] - 0 subjects analyzed

[89] - 0 subjects analyzed

[90] - 0 subjects analyzed

[91] - 0 subjects analyzed

| End point values            | BMS-986148<br>0.8MG/KG<br>Q3W+Nivolumab |  |  |  |
|-----------------------------|-----------------------------------------|--|--|--|
| Subject group type          | Reporting group                         |  |  |  |
| Number of subjects analysed | 0 <sup>[92]</sup>                       |  |  |  |
| Units: Participants         |                                         |  |  |  |
| ADA positive                |                                         |  |  |  |
| ADA negative                |                                         |  |  |  |

Notes:

[92] - 0 subjects analyzed

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

All adverse events were collected from the first dose up to 60 days (inclusive) after the last dose of BMS-986148

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 23.0 |
|--------------------|------|

### Reporting groups

|                       |                  |
|-----------------------|------------------|
| Reporting group title | BMS 0.2MG/KG Q3W |
|-----------------------|------------------|

Reporting group description:

Subjects were intravenously administered with monotherapy of 0.2 mg/kg BMS-986148 every 3 weeks.

|                       |                  |
|-----------------------|------------------|
| Reporting group title | BMS 0.1MG/KG Q3W |
|-----------------------|------------------|

Reporting group description:

Subjects were intravenously administered with monotherapy of 0.1 milligrams per kilograms (mg/kg) BMS-986148 every 3 weeks.

|                       |                  |
|-----------------------|------------------|
| Reporting group title | BMS 0.8MG/KG Q3W |
|-----------------------|------------------|

Reporting group description:

Subjects were intravenously administered with monotherapy of 0.8 mg/kg BMS-986148 every 3 weeks.

|                       |                  |
|-----------------------|------------------|
| Reporting group title | BMS 0.4MG/KG Q3W |
|-----------------------|------------------|

Reporting group description:

Subjects were intravenously administered with monotherapy of 0.4 mg/kg BMS-986148 every 3 weeks.

|                       |                  |
|-----------------------|------------------|
| Reporting group title | BMS 1.6MG/KG Q3W |
|-----------------------|------------------|

Reporting group description:

Subjects were intravenously administered with monotherapy of 1.6 mg/kg BMS-986148 every 3 weeks.

|                       |                 |
|-----------------------|-----------------|
| Reporting group title | BMS 0.4MG/KG QW |
|-----------------------|-----------------|

Reporting group description:

Subjects were intravenously administered with monotherapy of 0.4 mg/kg BMS-986148 weekly for 3 weeks with one week off.

|                       |                  |
|-----------------------|------------------|
| Reporting group title | BMS 1.2MG/KG Q3W |
|-----------------------|------------------|

Reporting group description:

Subjects were intravenously administered with monotherapy of 1.2 mg/kg BMS-986148 every 3 weeks.

|                       |                 |
|-----------------------|-----------------|
| Reporting group title | BMS 0.6MG/KG QW |
|-----------------------|-----------------|

Reporting group description:

Subjects were intravenously administered with monotherapy of 0.6 mg/kg BMS-986148 weekly for 3 weeks with one week off.

|                       |                    |
|-----------------------|--------------------|
| Reporting group title | BMS 0.8MG/KG Q3W+N |
|-----------------------|--------------------|

Reporting group description:

Subjects were intravenously administered with combination therapy of BMS-986148 and nivolumab. The starting dose of 0.8 mg/kg BMS-986148 to be combined with nivolumab at 360 mg every 3 weeks. Followed by escalation to 1.2 mg/kg of BMS-986148 in combination with nivolumab 360 mg every 3 weeks.

| Serious adverse events                            | BMS 0.2MG/KG Q3W | BMS 0.1MG/KG Q3W | BMS 0.8MG/KG Q3W |
|---------------------------------------------------|------------------|------------------|------------------|
| Total subjects affected by serious adverse events |                  |                  |                  |
| subjects affected / exposed                       | 1 / 2 (50.00%)   | 1 / 2 (50.00%)   | 6 / 8 (75.00%)   |
| number of deaths (all causes)                     | 2                | 1                | 5                |

|                                                                     |                |               |                |
|---------------------------------------------------------------------|----------------|---------------|----------------|
| number of deaths resulting from adverse events                      |                |               |                |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                |               |                |
| Malignant neoplasm progression                                      |                |               |                |
| subjects affected / exposed                                         | 1 / 2 (50.00%) | 0 / 2 (0.00%) | 3 / 8 (37.50%) |
| occurrences causally related to treatment / all                     | 0 / 1          | 0 / 0         | 0 / 3          |
| deaths causally related to treatment / all                          | 0 / 1          | 0 / 0         | 0 / 3          |
| Neoplasm malignant                                                  |                |               |                |
| subjects affected / exposed                                         | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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                                                  |                |               |                |
| Venous thrombosis                                                   |                |               |                |
| subjects affected / exposed                                         | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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                |                |               |                |
| Chest pain                                                          |                |               |                |
| subjects affected / exposed                                         | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0         | 0 / 0          |
| Infusion site extravasation                                         |                |               |                |
| subjects affected / exposed                                         | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0         | 0 / 0          |
| Malaise                                                             |                |               |                |

|                                                 |               |               |                |
|-------------------------------------------------|---------------|---------------|----------------|
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |
| Non-cardiac chest pain                          |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 1          |
| Pyrexia                                         |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 |               |               |                |
| Dyspnoea                                        |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |
| Interstitial lung disease                       |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |
| Pleurisy                                        |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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                                  |               |               |               |
| Blood creatinine increased                      |               |               |               |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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 necrosis marker increased            |               |               |               |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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  |               |               |               |
| Subdural haematoma                              |               |               |               |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Toxicity to various agents                      |               |               |               |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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                               |               |               |               |
| Atrial fibrillation                             |               |               |               |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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 flutter                                  |               |               |               |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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 failure                                 |               |               |               |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Pericarditis                                    |               |               |               |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |
| Tachycardia                                     |               |               |               |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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                        |               |               |               |
| Depressed level of consciousness                |               |               |               |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0         |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Neuralgia                                       |               |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%) | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Ascites                                         |               |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%) | 1 / 2 (50.00%) | 0 / 8 (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          |
| Duodenal obstruction                            |               |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 obstruction                    |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |
| Ileus                                           |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |
| Ileus paralytic                                 |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |
| Impaired gastric emptying                       |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| 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 obstruction                          |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |
| Intra-abdominal haemorrhage                     |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Rectal haemorrhage                              |                |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%)  | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 2          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Subileus                                        |                |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Abdominal wall haematoma                        |                |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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                         |                |               |                |
| Bile duct obstruction                           |                |               |                |
| subjects affected / exposed                     | 1 / 2 (50.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Bile duct stenosis                              |                |               |                |

|                                                 |               |               |                |
|-------------------------------------------------|---------------|---------------|----------------|
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |
| Cholangitis                                     |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |
| Drug-induced liver injury                       |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |
| Hyperbilirubinaemia                             |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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                                        |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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                     |               |               |                |
| Urinary tract obstruction                       |               |               |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| 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 |               |               |                |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Arthralgia                                      |               |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Back pain                                       |               |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 1 / 2 (50.00%) | 0 / 8 (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          |
| Muscular weakness                               |               |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| 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                     |               |                |                |
| Abdominal infection                             |               |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Lymphangitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Peritonitis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 2 (0.00%) | 1 / 2 (50.00%) | 0 / 8 (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          |
| Sepsis                                          |               |                |                |

|                                                 |               |               |               |
|-------------------------------------------------|---------------|---------------|---------------|
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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              |               |               |               |
| Dehydration                                     |               |               |               |
| subjects affected / exposed                     | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| 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>                                       | <b>BMS 0.4MG/KG Q3W</b> | <b>BMS 1.6MG/KG Q3W</b> | <b>BMS 0.4MG/KG QW</b> |
|---------------------------------------------------------------------|-------------------------|-------------------------|------------------------|
| Total subjects affected by serious adverse events                   |                         |                         |                        |
| subjects affected / exposed                                         | 1 / 3 (33.33%)          | 4 / 10 (40.00%)         | 6 / 8 (75.00%)         |
| number of deaths (all causes)                                       | 3                       | 7                       | 7                      |
| number of deaths resulting from adverse events                      |                         |                         |                        |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                         |                         |                        |
| Malignant neoplasm progression                                      |                         |                         |                        |
| subjects affected / exposed                                         | 0 / 3 (0.00%)           | 0 / 10 (0.00%)          | 2 / 8 (25.00%)         |
| occurrences causally related to treatment / all                     | 0 / 0                   | 0 / 0                   | 0 / 2                  |
| deaths causally related to treatment / all                          | 0 / 0                   | 0 / 0                   | 0 / 2                  |
| Neoplasm malignant                                                  |                         |                         |                        |
| subjects affected / exposed                                         | 0 / 3 (0.00%)           | 0 / 10 (0.00%)          | 0 / 8 (0.00%)          |
| 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 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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                                   |               |                |               |
| Venous thrombosis                                    |               |                |               |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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 |               |                |               |
| Chest pain                                           |               |                |               |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0         |
| Infusion site extravasation                          |               |                |               |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0         |
| Malaise                                              |               |                |               |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all           | 0 / 0         | 0 / 0          | 0 / 0         |
| Non-cardiac chest pain                               |               |                |               |
| subjects affected / exposed                          | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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 |               |                 |                |
| Dyspnoea                                        |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Interstitial lung disease                       |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Pleurisy                                        |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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%) | 1 / 10 (10.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Pneumonitis                                     |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 10 (10.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |

|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| Investigations                                  |               |                 |                |
| Blood creatinine increased                      |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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 necrosis marker increased            |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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  |               |                 |                |
| Subdural haematoma                              |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Toxicity to various agents                      |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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                               |               |                 |                |
| Atrial fibrillation                             |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Atrial flutter                                  |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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 failure                                 |               |                 |                |

|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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%) | 1 / 10 (10.00%) | 0 / 8 (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          |
| Pericarditis                                    |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Tachycardia                                     |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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                        |               |                 |                |
| Depressed level of consciousness                |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Neuralgia                                       |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 1          |
| Syncope                                         |               |                 |                |

|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| 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 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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%) | 2 / 10 (20.00%) | 0 / 8 (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          |
| Ascites                                         |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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 obstruction                            |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| 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 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Gastrointestinal obstruction                    |               |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Ileus                                           |               |                 |                |

|                                                 |               |                |               |
|-------------------------------------------------|---------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Ileus paralytic                                 |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Impaired gastric emptying                       |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Intra-abdominal haemorrhage                     |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Rectal haemorrhage                              |               |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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                     | 1 / 3 (33.33%) | 0 / 10 (0.00%) | 0 / 8 (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         |
| Subileus                                        |                |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Abdominal wall haematoma                        |                |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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                         |                |                |               |
| Bile duct obstruction                           |                |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Bile duct stenosis                              |                |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Cholangitis                                     |                |                |               |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Drug-induced liver injury                       |                |                |               |

|                                                 |               |                 |               |
|-------------------------------------------------|---------------|-----------------|---------------|
| subjects affected / exposed                     | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 0 / 8 (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         |
| Hepatitis                                       |               |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0         |
| Hyperbilirubinaemia                             |               |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%) |
| 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 / 10 (0.00%)  | 0 / 8 (0.00%) |
| 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                                        |               |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%) |
| 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                     |               |                 |               |
| Urinary tract obstruction                       |               |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%) |
| 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 |               |                 |               |
| Arthralgia                                      |               |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0         |
| Back pain                                       |               |                 |               |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0         |

|                                                 |               |                |                |
|-------------------------------------------------|---------------|----------------|----------------|
| Muscular weakness                               |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%)  |
| 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 / 10 (0.00%) | 0 / 8 (0.00%)  |
| 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                     |               |                |                |
| Abdominal infection                             |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Lymphangitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Peritonitis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%)  |
| 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%) | 0 / 10 (0.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Sepsis                                          |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%)  |
| 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              |               |                |                |
| Dehydration                                     |               |                |                |
| subjects affected / exposed                     | 0 / 3 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%)  |
| 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 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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 / 10 (0.00%) | 0 / 8 (0.00%) |
| 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>                                       | BMS 1.2MG/KG Q3W | BMS 0.6MG/KG QW | BMS 0.8MG/KG Q3W+N |
|---------------------------------------------------------------------|------------------|-----------------|--------------------|
| Total subjects affected by serious adverse events                   |                  |                 |                    |
| subjects affected / exposed                                         | 34 / 59 (57.63%) | 3 / 4 (75.00%)  | 22 / 30 (73.33%)   |
| number of deaths (all causes)                                       | 38               | 4               | 22                 |
| number of deaths resulting from adverse events                      |                  |                 |                    |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                  |                 |                    |
| Malignant neoplasm progression                                      |                  |                 |                    |
| subjects affected / exposed                                         | 14 / 59 (23.73%) | 2 / 4 (50.00%)  | 10 / 30 (33.33%)   |
| occurrences causally related to treatment / all                     | 0 / 14           | 0 / 2           | 0 / 10             |
| deaths causally related to treatment / all                          | 0 / 14           | 0 / 2           | 0 / 8              |
| Neoplasm malignant                                                  |                  |                 |                    |
| subjects affected / exposed                                         | 0 / 59 (0.00%)   | 0 / 4 (0.00%)   | 1 / 30 (3.33%)     |
| 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                                         | 1 / 59 (1.69%)   | 1 / 4 (25.00%)  | 0 / 30 (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              |
| Tumour haemorrhage                                                  |                  |                 |                    |
| subjects affected / exposed                                         | 0 / 59 (0.00%)   | 0 / 4 (0.00%)   | 1 / 30 (3.33%)     |
| occurrences causally related to treatment / all                     | 0 / 0            | 0 / 0           | 0 / 1              |
| deaths causally related to treatment / all                          | 0 / 0            | 0 / 0           | 0 / 1              |
| Vascular disorders                                                  |                  |                 |                    |
| Venous thrombosis                                                   |                  |                 |                    |

|                                                      |                |               |                |
|------------------------------------------------------|----------------|---------------|----------------|
| subjects affected / exposed                          | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0         | 0 / 0          |
| General disorders and administration site conditions |                |               |                |
| Chest pain                                           |                |               |                |
| subjects affected / exposed                          | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Infusion site extravasation                          |                |               |                |
| subjects affected / exposed                          | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0         | 0 / 0          |
| Malaise                                              |                |               |                |
| subjects affected / exposed                          | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Non-cardiac chest pain                               |                |               |                |
| subjects affected / exposed                          | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0         | 0 / 0          |
| Performance status decreased                         |                |               |                |
| subjects affected / exposed                          | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| 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 / 59 (1.69%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0         | 0 / 2          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0         | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders      |                |               |                |
| Dyspnoea                                             |                |               |                |
| subjects affected / exposed                          | 2 / 59 (3.39%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all      | 0 / 3          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0         | 0 / 0          |

|                                                 |                |               |                |
|-------------------------------------------------|----------------|---------------|----------------|
| Interstitial lung disease                       |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Pleural effusion                                |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Pleurisy                                        |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Pleuritic pain                                  |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| 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                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 1          | 0 / 0         | 0 / 0          |
| Pulmonary embolism                              |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| 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                                  |                |               |                |
| Blood creatinine increased                      |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Myocardial necrosis marker increased            |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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 / 59 (0.00%) | 0 / 4 (0.00%) | 2 / 30 (6.67%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 2          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Injury, poisoning and procedural complications  |                |               |                |
| Subdural haematoma                              |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Toxicity to various agents                      |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Cardiac disorders                               |                |               |                |
| Atrial fibrillation                             |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| 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 flutter                                  |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Cardiac failure                                 |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 1          |
| Cardio-respiratory arrest                       |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Pericardial effusion                            |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |

|                                                 |                |               |                |
|-------------------------------------------------|----------------|---------------|----------------|
| Pericarditis                                    |                |               |                |
| subjects affected / exposed                     | 2 / 59 (3.39%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 2          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Tachycardia                                     |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Nervous system disorders                        |                |               |                |
| Depressed level of consciousness                |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 1          |
| Neuralgia                                       |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Paraparesis                                     |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| 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 / 59 (0.00%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| 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 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Gastrointestinal disorders                      |                |               |                |
| Abdominal pain                                  |                |               |                |

|                                                 |                |                |                 |
|-------------------------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed                     | 3 / 59 (5.08%) | 1 / 4 (25.00%) | 0 / 30 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 4          | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 1          | 0 / 0           |
| Ascites                                         |                |                |                 |
| subjects affected / exposed                     | 4 / 59 (6.78%) | 0 / 4 (0.00%)  | 3 / 30 (10.00%) |
| occurrences causally related to treatment / all | 0 / 5          | 0 / 0          | 0 / 3           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Diarrhoea                                       |                |                |                 |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%)  | 0 / 30 (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           |
| Duodenal obstruction                            |                |                |                 |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 1 / 30 (3.33%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Dysphagia                                       |                |                |                 |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| 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 obstruction                    |                |                |                 |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 1 / 30 (3.33%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Ileus                                           |                |                |                 |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%)  | 0 / 30 (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           |
| Ileus paralytic                                 |                |                |                 |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%)  | 0 / 30 (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           |
| Impaired gastric emptying                       |                |                |                 |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%) |
| 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 / 59 (0.00%) | 0 / 4 (0.00%)  | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Intestinal perforation                          |                |                |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Intra-abdominal haemorrhage                     |                |                |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Nausea                                          |                |                |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 1 / 4 (25.00%) | 0 / 30 (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          |
| Rectal haemorrhage                              |                |                |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%)  | 0 / 30 (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          |
| Small intestinal obstruction                    |                |                |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%)  | 0 / 30 (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          |
| Subileus                                        |                |                |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%)  | 0 / 30 (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          |
| Vomiting                                        |                |                |                |

|                                                 |                |               |                |
|-------------------------------------------------|----------------|---------------|----------------|
| subjects affected / exposed                     | 2 / 59 (3.39%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Abdominal wall haematoma                        |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Pancreatitis                                    |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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                         |                |               |                |
| Bile duct obstruction                           |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Bile duct stenosis                              |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Cholangitis                                     |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Drug-induced liver injury                       |                |               |                |
| subjects affected / exposed                     | 2 / 59 (3.39%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 2          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Hepatitis                                       |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Hyperbilirubinaemia                             |                |               |                |

|                                                 |                |               |                |
|-------------------------------------------------|----------------|---------------|----------------|
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| 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 hepatitis                       |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Jaundice                                        |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Renal and urinary disorders                     |                |               |                |
| Urinary tract obstruction                       |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Musculoskeletal and connective tissue disorders |                |               |                |
| Arthralgia                                      |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Back pain                                       |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Muscular weakness                               |                |               |                |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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          |
| Musculoskeletal chest pain                      |                |               |                |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |

|                                                 |                |               |                 |
|-------------------------------------------------|----------------|---------------|-----------------|
| Infections and infestations                     |                |               |                 |
| Abdominal infection                             |                |               |                 |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0           |
| Lymphangitis                                    |                |               |                 |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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           |
| Peritonitis                                     |                |               |                 |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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           |
| Pneumonia                                       |                |               |                 |
| subjects affected / exposed                     | 2 / 59 (3.39%) | 0 / 4 (0.00%) | 4 / 30 (13.33%) |
| occurrences causally related to treatment / all | 0 / 2          | 0 / 0         | 0 / 5           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0           |
| Sepsis                                          |                |               |                 |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 2          | 0 / 0         | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0           |
| Metabolism and nutrition disorders              |                |               |                 |
| Dehydration                                     |                |               |                 |
| subjects affected / exposed                     | 0 / 59 (0.00%) | 0 / 4 (0.00%) | 1 / 30 (3.33%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0           |
| Hypoglycaemia                                   |                |               |                 |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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           |
| Hyponatraemia                                   |                |               |                 |
| subjects affected / exposed                     | 1 / 59 (1.69%) | 0 / 4 (0.00%) | 0 / 30 (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           |

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

| <b>Non-serious adverse events</b>                                   | <b>BMS 0.2MG/KG Q3W</b> | <b>BMS 0.1MG/KG Q3W</b> | <b>BMS 0.8MG/KG Q3W</b> |
|---------------------------------------------------------------------|-------------------------|-------------------------|-------------------------|
| Total subjects affected by non-serious adverse events               |                         |                         |                         |
| subjects affected / exposed                                         | 2 / 2 (100.00%)         | 1 / 2 (50.00%)          | 8 / 8 (100.00%)         |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                         |                         |                         |
| Tumour pain                                                         |                         |                         |                         |
| subjects affected / exposed                                         | 0 / 2 (0.00%)           | 0 / 2 (0.00%)           | 0 / 8 (0.00%)           |
| occurrences (all)                                                   | 0                       | 0                       | 0                       |
| Vascular disorders                                                  |                         |                         |                         |
| Hypertension                                                        |                         |                         |                         |
| subjects affected / exposed                                         | 0 / 2 (0.00%)           | 0 / 2 (0.00%)           | 0 / 8 (0.00%)           |
| occurrences (all)                                                   | 0                       | 0                       | 0                       |
| Systolic hypertension                                               |                         |                         |                         |
| subjects affected / exposed                                         | 0 / 2 (0.00%)           | 0 / 2 (0.00%)           | 0 / 8 (0.00%)           |
| occurrences (all)                                                   | 0                       | 0                       | 0                       |
| Flushing                                                            |                         |                         |                         |
| subjects affected / exposed                                         | 0 / 2 (0.00%)           | 0 / 2 (0.00%)           | 1 / 8 (12.50%)          |
| occurrences (all)                                                   | 0                       | 0                       | 1                       |
| Hypotension                                                         |                         |                         |                         |
| subjects affected / exposed                                         | 0 / 2 (0.00%)           | 0 / 2 (0.00%)           | 1 / 8 (12.50%)          |
| occurrences (all)                                                   | 0                       | 0                       | 2                       |
| General disorders and administration site conditions                |                         |                         |                         |
| Asthenia                                                            |                         |                         |                         |
| subjects affected / exposed                                         | 0 / 2 (0.00%)           | 0 / 2 (0.00%)           | 1 / 8 (12.50%)          |
| occurrences (all)                                                   | 0                       | 0                       | 2                       |
| Chest discomfort                                                    |                         |                         |                         |
| subjects affected / exposed                                         | 0 / 2 (0.00%)           | 0 / 2 (0.00%)           | 0 / 8 (0.00%)           |
| occurrences (all)                                                   | 0                       | 0                       | 0                       |
| Chest pain                                                          |                         |                         |                         |
| subjects affected / exposed                                         | 0 / 2 (0.00%)           | 0 / 2 (0.00%)           | 0 / 8 (0.00%)           |
| occurrences (all)                                                   | 0                       | 0                       | 0                       |

|                                          |                |                |                |
|------------------------------------------|----------------|----------------|----------------|
| Chills                                   |                |                |                |
| subjects affected / exposed              | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 0              | 0              |
| Fatigue                                  |                |                |                |
| subjects affected / exposed              | 1 / 2 (50.00%) | 0 / 2 (0.00%)  | 5 / 8 (62.50%) |
| occurrences (all)                        | 2              | 0              | 19             |
| Influenza like illness                   |                |                |                |
| subjects affected / exposed              | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 0              | 0              |
| Malaise                                  |                |                |                |
| subjects affected / exposed              | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 0              | 0              |
| Non-cardiac chest pain                   |                |                |                |
| subjects affected / exposed              | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 0              | 0              |
| Oedema peripheral                        |                |                |                |
| subjects affected / exposed              | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                        | 0              | 0              | 1              |
| Pyrexia                                  |                |                |                |
| subjects affected / exposed              | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 0              | 0              |
| Early satiety                            |                |                |                |
| subjects affected / exposed              | 1 / 2 (50.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                        | 1              | 0              | 0              |
| Mucosal inflammation                     |                |                |                |
| subjects affected / exposed              | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                        | 0              | 0              | 1              |
| Pain                                     |                |                |                |
| subjects affected / exposed              | 0 / 2 (0.00%)  | 1 / 2 (50.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 1              | 0              |
| Immune system disorders                  |                |                |                |
| Hypersensitivity                         |                |                |                |
| subjects affected / exposed              | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 0              | 0              |
| Reproductive system and breast disorders |                |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| Testicular pain                                 |                |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0              |
| Pelvic pain                                     |                |                |                |
| subjects affected / exposed                     | 1 / 2 (50.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 1              | 0              | 0              |
| Respiratory, thoracic and mediastinal disorders |                |                |                |
| Cough                                           |                |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 3 / 8 (37.50%) |
| occurrences (all)                               | 0              | 0              | 3              |
| Dysphonia                                       |                |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0              |
| Dyspnoea                                        |                |                |                |
| subjects affected / exposed                     | 1 / 2 (50.00%) | 1 / 2 (50.00%) | 1 / 8 (12.50%) |
| occurrences (all)                               | 1              | 1              | 1              |
| Dyspnoea exertional                             |                |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                               | 0              | 0              | 2              |
| Epistaxis                                       |                |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0              |
| Oropharyngeal pain                              |                |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0              |
| Pleural effusion                                |                |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0              |
| Pleuritic pain                                  |                |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                               | 0              | 0              | 1              |
| Productive cough                                |                |                |                |
| subjects affected / exposed                     | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0              |
| Rales                                           |                |                |                |

|                             |               |                |                |
|-----------------------------|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Throat irritation           |               |                |                |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Haemoptysis                 |               |                |                |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 2 (50.00%) | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 1              | 0              |
| Hiccups                     |               |                |                |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)           | 0             | 0              | 1              |
| Hypoxia                     |               |                |                |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Nasal congestion            |               |                |                |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Psychiatric disorders       |               |                |                |
| Abnormal dreams             |               |                |                |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Anxiety                     |               |                |                |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Confusional state           |               |                |                |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)           | 0             | 0              | 1              |
| Delirium                    |               |                |                |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Hallucination, auditory     |               |                |                |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 0              | 0              |
| Insomnia                    |               |                |                |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%)  | 2 / 8 (25.00%) |
| occurrences (all)           | 0             | 0              | 2              |

|                                      |                |               |                |
|--------------------------------------|----------------|---------------|----------------|
| Depression                           |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)                    | 0              | 0             | 4              |
| Hallucination                        |                |               |                |
| subjects affected / exposed          | 1 / 2 (50.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 1              | 0             | 0              |
| Investigations                       |                |               |                |
| Alanine aminotransferase increased   |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all)                    | 0              | 0             | 2              |
| Aspartate aminotransferase increased |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 3 / 8 (37.50%) |
| occurrences (all)                    | 0              | 0             | 3              |
| Blood alkaline phosphatase increased |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Blood bilirubin increased            |                |               |                |
| subjects affected / exposed          | 1 / 2 (50.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)                    | 1              | 0             | 1              |
| Blood creatinine increased           |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Electrocardiogram QT prolonged       |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Gamma-glutamyltransferase increased  |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Lymphocyte count decreased           |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Platelet count decreased             |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Weight decreased                     |                |               |                |

|                                                                                   |                     |                    |                     |
|-----------------------------------------------------------------------------------|---------------------|--------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                                  | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0 | 3 / 8 (37.50%)<br>5 |
| Blood sodium increased<br>subjects affected / exposed<br>occurrences (all)        | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  |
| Liver function test increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  |
| Injury, poisoning and procedural complications                                    |                     |                    |                     |
| Fall<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  |
| Head injury<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  |
| Cardiac disorders                                                                 |                     |                    |                     |
| Atrial fibrillation<br>subjects affected / exposed<br>occurrences (all)           | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0 | 1 / 8 (12.50%)<br>1 |
| Mitral valve incompetence<br>subjects affected / exposed<br>occurrences (all)     | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  |
| Pericarditis<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  |
| Sinus bradycardia<br>subjects affected / exposed<br>occurrences (all)             | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  |
| Tachycardia<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  |
| Nervous system disorders                                                          |                     |                    |                     |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                     | 1 / 2 (50.00%)<br>2 | 0 / 2 (0.00%)<br>0 | 2 / 8 (25.00%)<br>3 |
| Dysarthria                                                                        |                     |                    |                     |

|                                      |                |               |                |
|--------------------------------------|----------------|---------------|----------------|
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Dysgeusia                            |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Headache                             |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)                    | 0              | 0             | 1              |
| Neuropathy peripheral                |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)                    | 0              | 0             | 1              |
| Peripheral sensory neuropathy        |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Horner's syndrome                    |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Seizure                              |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)                    | 0              | 0             | 1              |
| Somnolence                           |                |               |                |
| subjects affected / exposed          | 1 / 2 (50.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 2              | 0             | 0              |
| Blood and lymphatic system disorders |                |               |                |
| Anaemia                              |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Lymphopenia                          |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Thrombocytopenia                     |                |               |                |
| subjects affected / exposed          | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0              | 0             | 0              |
| Eye disorders                        |                |               |                |
| Blepharitis                          |                |               |                |

|                               |               |               |                |
|-------------------------------|---------------|---------------|----------------|
| subjects affected / exposed   | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0             | 0              |
| Cataract                      |               |               |                |
| subjects affected / exposed   | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0             | 0              |
| Dry eye                       |               |               |                |
| subjects affected / exposed   | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all)             | 0             | 0             | 2              |
| Strabismus                    |               |               |                |
| subjects affected / exposed   | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0             | 0              |
| Vision blurred                |               |               |                |
| subjects affected / exposed   | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0             | 0              |
| Vitreous floaters             |               |               |                |
| subjects affected / exposed   | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0             | 0              |
| Chalazion                     |               |               |                |
| subjects affected / exposed   | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0             | 0              |
| Eye pain                      |               |               |                |
| subjects affected / exposed   | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)             | 0             | 0             | 1              |
| Lacrimation increased         |               |               |                |
| subjects affected / exposed   | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)             | 0             | 0             | 1              |
| Narrow anterior chamber angle |               |               |                |
| subjects affected / exposed   | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)             | 0             | 0             | 1              |
| Swelling of eyelid            |               |               |                |
| subjects affected / exposed   | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)             | 0             | 0             | 1              |
| Visual impairment             |               |               |                |
| subjects affected / exposed   | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)             | 0             | 0             | 1              |
| Gastrointestinal disorders    |               |               |                |

|                             |                |               |                |
|-----------------------------|----------------|---------------|----------------|
| Abdominal distension        |                |               |                |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 2 (0.00%) | 3 / 8 (37.50%) |
| occurrences (all)           | 1              | 0             | 5              |
| Abdominal pain              |                |               |                |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 2 (0.00%) | 3 / 8 (37.50%) |
| occurrences (all)           | 1              | 0             | 4              |
| Abdominal pain lower        |                |               |                |
| subjects affected / exposed | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)           | 0              | 0             | 1              |
| Abdominal pain upper        |                |               |                |
| subjects affected / exposed | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)           | 0              | 0             | 0              |
| Ascites                     |                |               |                |
| subjects affected / exposed | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)           | 0              | 0             | 5              |
| Breath odour                |                |               |                |
| subjects affected / exposed | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)           | 0              | 0             | 0              |
| Constipation                |                |               |                |
| subjects affected / exposed | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)           | 0              | 0             | 0              |
| Diarrhoea                   |                |               |                |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 2 (0.00%) | 3 / 8 (37.50%) |
| occurrences (all)           | 1              | 0             | 4              |
| Dry mouth                   |                |               |                |
| subjects affected / exposed | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)           | 0              | 0             | 0              |
| Dyspepsia                   |                |               |                |
| subjects affected / exposed | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 3 / 8 (37.50%) |
| occurrences (all)           | 0              | 0             | 4              |
| Dysphagia                   |                |               |                |
| subjects affected / exposed | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)           | 0              | 0             | 0              |
| Eructation                  |                |               |                |
| subjects affected / exposed | 0 / 2 (0.00%)  | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)           | 0              | 0             | 0              |

|                                  |                |                |                |
|----------------------------------|----------------|----------------|----------------|
| Flatulence                       |                |                |                |
| subjects affected / exposed      | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                | 0              | 0              | 1              |
| Gastrooesophageal reflux disease |                |                |                |
| subjects affected / exposed      | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                | 0              | 0              | 0              |
| Haemorrhoids                     |                |                |                |
| subjects affected / exposed      | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                | 0              | 0              | 1              |
| Nausea                           |                |                |                |
| subjects affected / exposed      | 1 / 2 (50.00%) | 1 / 2 (50.00%) | 5 / 8 (62.50%) |
| occurrences (all)                | 1              | 1              | 7              |
| Rectal haemorrhage               |                |                |                |
| subjects affected / exposed      | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                | 0              | 0              | 0              |
| Stomatitis                       |                |                |                |
| subjects affected / exposed      | 0 / 2 (0.00%)  | 1 / 2 (50.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                | 0              | 1              | 0              |
| Swollen tongue                   |                |                |                |
| subjects affected / exposed      | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                | 0              | 0              | 0              |
| Vomiting                         |                |                |                |
| subjects affected / exposed      | 1 / 2 (50.00%) | 0 / 2 (0.00%)  | 4 / 8 (50.00%) |
| occurrences (all)                | 2              | 0              | 4              |
| Abdominal discomfort             |                |                |                |
| subjects affected / exposed      | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                | 0              | 0              | 1              |
| Impaired gastric emptying        |                |                |                |
| subjects affected / exposed      | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                | 0              | 0              | 1              |
| Retching                         |                |                |                |
| subjects affected / exposed      | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                | 0              | 0              | 0              |
| Umbilical hernia                 |                |                |                |
| subjects affected / exposed      | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                | 0              | 0              | 1              |

|                                        |               |               |                |
|----------------------------------------|---------------|---------------|----------------|
| Hepatobiliary disorders                |               |               |                |
| Hyperbilirubinaemia                    |               |               |                |
| subjects affected / exposed            | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0             | 0             | 0              |
| Skin and subcutaneous tissue disorders |               |               |                |
| Dry skin                               |               |               |                |
| subjects affected / exposed            | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)                      | 0             | 0             | 1              |
| Pruritus                               |               |               |                |
| subjects affected / exposed            | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0             | 0             | 0              |
| Rash                                   |               |               |                |
| subjects affected / exposed            | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0             | 0             | 0              |
| Rash papular                           |               |               |                |
| subjects affected / exposed            | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0             | 0             | 0              |
| Skin odour abnormal                    |               |               |                |
| subjects affected / exposed            | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0             | 0             | 0              |
| Night sweats                           |               |               |                |
| subjects affected / exposed            | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0             | 0             | 0              |
| Rash macular                           |               |               |                |
| subjects affected / exposed            | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0             | 0             | 0              |
| Renal and urinary disorders            |               |               |                |
| Acute kidney injury                    |               |               |                |
| subjects affected / exposed            | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0             | 0             | 0              |
| Chromaturia                            |               |               |                |
| subjects affected / exposed            | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0             | 0             | 0              |
| Nocturia                               |               |               |                |
| subjects affected / exposed            | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0             | 0             | 0              |
| Proteinuria                            |               |               |                |

|                                                                                           |                     |                     |                     |
|-------------------------------------------------------------------------------------------|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                                          | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Urine odour abnormal<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Urinary retention<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Endocrine disorders<br>Hypothyroidism<br>subjects affected / exposed<br>occurrences (all) | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Musculoskeletal and connective tissue disorders                                           |                     |                     |                     |
| Arthralgia<br>subjects affected / exposed<br>occurrences (all)                            | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 |
| Back pain<br>subjects affected / exposed<br>occurrences (all)                             | 1 / 2 (50.00%)<br>1 | 1 / 2 (50.00%)<br>1 | 2 / 8 (25.00%)<br>3 |
| Flank pain<br>subjects affected / exposed<br>occurrences (all)                            | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Muscle spasms<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Muscular weakness<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Musculoskeletal chest pain<br>subjects affected / exposed<br>occurrences (all)            | 0 / 2 (0.00%)<br>0  | 0 / 2 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 |
| Musculoskeletal pain<br>subjects affected / exposed<br>occurrences (all)                  | 1 / 2 (50.00%)<br>1 | 0 / 2 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Myalgia                                                                                   |                     |                     |                     |

|                                   |               |               |                |
|-----------------------------------|---------------|---------------|----------------|
| subjects affected / exposed       | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0             | 0              |
| Pain in extremity                 |               |               |                |
| subjects affected / exposed       | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0             | 0              |
| Groin pain                        |               |               |                |
| subjects affected / exposed       | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0             | 0              |
| Musculoskeletal discomfort        |               |               |                |
| subjects affected / exposed       | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)                 | 0             | 0             | 1              |
| Neck pain                         |               |               |                |
| subjects affected / exposed       | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0             | 0              |
| Infections and infestations       |               |               |                |
| Nasopharyngitis                   |               |               |                |
| subjects affected / exposed       | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0             | 0              |
| Pneumonia                         |               |               |                |
| subjects affected / exposed       | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0             | 0              |
| Upper respiratory tract infection |               |               |                |
| subjects affected / exposed       | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0             | 0              |
| Urinary tract infection           |               |               |                |
| subjects affected / exposed       | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0             | 0              |
| Conjunctivitis                    |               |               |                |
| subjects affected / exposed       | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)                 | 0             | 0             | 1              |
| Cystitis                          |               |               |                |
| subjects affected / exposed       | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0             | 0              |
| Lower respiratory tract infection |               |               |                |
| subjects affected / exposed       | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all)                 | 0             | 0             | 1              |

|                                    |                |                |                |
|------------------------------------|----------------|----------------|----------------|
| Oral herpes                        |                |                |                |
| subjects affected / exposed        | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0              |
| Respiratory tract infection        |                |                |                |
| subjects affected / exposed        | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                  | 0              | 0              | 1              |
| Metabolism and nutrition disorders |                |                |                |
| Decreased appetite                 |                |                |                |
| subjects affected / exposed        | 1 / 2 (50.00%) | 0 / 2 (0.00%)  | 6 / 8 (75.00%) |
| occurrences (all)                  | 1              | 0              | 8              |
| Dehydration                        |                |                |                |
| subjects affected / exposed        | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                  | 0              | 0              | 1              |
| Hyperglycaemia                     |                |                |                |
| subjects affected / exposed        | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                  | 0              | 0              | 2              |
| Hyperuricaemia                     |                |                |                |
| subjects affected / exposed        | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0              |
| Hypoalbuminaemia                   |                |                |                |
| subjects affected / exposed        | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0              |
| Hypokalaemia                       |                |                |                |
| subjects affected / exposed        | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                  | 0              | 0              | 1              |
| Hypomagnesaemia                    |                |                |                |
| subjects affected / exposed        | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 3 / 8 (37.50%) |
| occurrences (all)                  | 0              | 0              | 4              |
| Hyponatraemia                      |                |                |                |
| subjects affected / exposed        | 0 / 2 (0.00%)  | 0 / 2 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0              |
| Hypophosphataemia                  |                |                |                |
| subjects affected / exposed        | 0 / 2 (0.00%)  | 1 / 2 (50.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                  | 0              | 1              | 0              |
| Increased appetite                 |                |                |                |

|                             |               |               |               |
|-----------------------------|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |
| Hypoglycaemia               |               |               |               |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all)           | 0             | 0             | 0             |

| <b>Non-serious adverse events</b>                                   | <b>BMS 0.4MG/KG Q3W</b> | <b>BMS 1.6MG/KG Q3W</b> | <b>BMS 0.4MG/KG QW</b> |
|---------------------------------------------------------------------|-------------------------|-------------------------|------------------------|
| Total subjects affected by non-serious adverse events               |                         |                         |                        |
| subjects affected / exposed                                         | 3 / 3 (100.00%)         | 10 / 10 (100.00%)       | 8 / 8 (100.00%)        |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                         |                         |                        |
| Tumour pain                                                         |                         |                         |                        |
| subjects affected / exposed                                         | 0 / 3 (0.00%)           | 1 / 10 (10.00%)         | 0 / 8 (0.00%)          |
| occurrences (all)                                                   | 0                       | 1                       | 0                      |
| Vascular disorders                                                  |                         |                         |                        |
| Hypertension                                                        |                         |                         |                        |
| subjects affected / exposed                                         | 0 / 3 (0.00%)           | 0 / 10 (0.00%)          | 0 / 8 (0.00%)          |
| occurrences (all)                                                   | 0                       | 0                       | 0                      |
| Systolic hypertension                                               |                         |                         |                        |
| subjects affected / exposed                                         | 0 / 3 (0.00%)           | 0 / 10 (0.00%)          | 1 / 8 (12.50%)         |
| occurrences (all)                                                   | 0                       | 0                       | 1                      |
| Flushing                                                            |                         |                         |                        |
| subjects affected / exposed                                         | 0 / 3 (0.00%)           | 0 / 10 (0.00%)          | 0 / 8 (0.00%)          |
| occurrences (all)                                                   | 0                       | 0                       | 0                      |
| Hypotension                                                         |                         |                         |                        |
| subjects affected / exposed                                         | 0 / 3 (0.00%)           | 2 / 10 (20.00%)         | 0 / 8 (0.00%)          |
| occurrences (all)                                                   | 0                       | 2                       | 0                      |
| General disorders and administration site conditions                |                         |                         |                        |
| Asthenia                                                            |                         |                         |                        |
| subjects affected / exposed                                         | 0 / 3 (0.00%)           | 0 / 10 (0.00%)          | 0 / 8 (0.00%)          |
| occurrences (all)                                                   | 0                       | 0                       | 0                      |
| Chest discomfort                                                    |                         |                         |                        |
| subjects affected / exposed                                         | 0 / 3 (0.00%)           | 0 / 10 (0.00%)          | 1 / 8 (12.50%)         |
| occurrences (all)                                                   | 0                       | 0                       | 1                      |
| Chest pain                                                          |                         |                         |                        |
| subjects affected / exposed                                         | 0 / 3 (0.00%)           | 0 / 10 (0.00%)          | 0 / 8 (0.00%)          |
| occurrences (all)                                                   | 0                       | 0                       | 0                      |

|                                          |                |                 |                |
|------------------------------------------|----------------|-----------------|----------------|
| Chills                                   |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 1               | 0              |
| Fatigue                                  |                |                 |                |
| subjects affected / exposed              | 1 / 3 (33.33%) | 8 / 10 (80.00%) | 3 / 8 (37.50%) |
| occurrences (all)                        | 1              | 15              | 4              |
| Influenza like illness                   |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 2               | 0              |
| Malaise                                  |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 1 / 8 (12.50%) |
| occurrences (all)                        | 0              | 1               | 1              |
| Non-cardiac chest pain                   |                |                 |                |
| subjects affected / exposed              | 1 / 3 (33.33%) | 1 / 10 (10.00%) | 3 / 8 (37.50%) |
| occurrences (all)                        | 1              | 1               | 6              |
| Oedema peripheral                        |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 2 / 10 (20.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 2               | 0              |
| Pyrexia                                  |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 3 / 10 (30.00%) | 1 / 8 (12.50%) |
| occurrences (all)                        | 0              | 3               | 1              |
| Early satiety                            |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 0               | 0              |
| Mucosal inflammation                     |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 1               | 0              |
| Pain                                     |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 1               | 0              |
| Immune system disorders                  |                |                 |                |
| Hypersensitivity                         |                |                 |                |
| subjects affected / exposed              | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                        | 0              | 1               | 0              |
| Reproductive system and breast disorders |                |                 |                |

|                                                 |                |                 |                |
|-------------------------------------------------|----------------|-----------------|----------------|
| Testicular pain                                 |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Pelvic pain                                     |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Respiratory, thoracic and mediastinal disorders |                |                 |                |
| Cough                                           |                |                 |                |
| subjects affected / exposed                     | 1 / 3 (33.33%) | 2 / 10 (20.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                               | 1              | 2               | 0              |
| Dysphonia                                       |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                               | 0              | 0               | 1              |
| Dyspnoea                                        |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 5 / 10 (50.00%) | 1 / 8 (12.50%) |
| occurrences (all)                               | 0              | 5               | 1              |
| Dyspnoea exertional                             |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                               | 0              | 0               | 2              |
| Epistaxis                                       |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 1               | 0              |
| Oropharyngeal pain                              |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 1               | 0              |
| Pleural effusion                                |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 2 / 8 (25.00%) |
| occurrences (all)                               | 0              | 0               | 2              |
| Pleuritic pain                                  |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 3 / 10 (30.00%) | 2 / 8 (25.00%) |
| occurrences (all)                               | 0              | 4               | 5              |
| Productive cough                                |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                               | 0              | 0               | 1              |
| Rales                                           |                |                 |                |

|                             |                |                 |                |
|-----------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Throat irritation           |                |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Haemoptysis                 |                |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0              |
| Hiccups                     |                |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 2 / 10 (20.00%) | 0 / 8 (0.00%)  |
| occurrences (all)           | 0              | 2               | 0              |
| Hypoxia                     |                |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0              |
| Nasal congestion            |                |                 |                |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 1              | 0               | 0              |
| Psychiatric disorders       |                |                 |                |
| Abnormal dreams             |                |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)           | 0              | 0               | 1              |
| Anxiety                     |                |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0              |
| Confusional state           |                |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)           | 0              | 0               | 1              |
| Delirium                    |                |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)           | 0              | 0               | 1              |
| Hallucination, auditory     |                |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)           | 0              | 0               | 1              |
| Insomnia                    |                |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)           | 0              | 0               | 1              |

|                                                                                          |                    |                       |                     |
|------------------------------------------------------------------------------------------|--------------------|-----------------------|---------------------|
| Depression<br>subjects affected / exposed<br>occurrences (all)                           | 0 / 3 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0   | 0 / 8 (0.00%)<br>0  |
| Hallucination<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 3 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0   | 0 / 8 (0.00%)<br>0  |
| Investigations                                                                           |                    |                       |                     |
| Alanine aminotransferase increased<br>subjects affected / exposed<br>occurrences (all)   | 0 / 3 (0.00%)<br>0 | 6 / 10 (60.00%)<br>10 | 3 / 8 (37.50%)<br>5 |
| Aspartate aminotransferase increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 3 (0.00%)<br>0 | 5 / 10 (50.00%)<br>12 | 2 / 8 (25.00%)<br>2 |
| Blood alkaline phosphatase increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 3 (0.00%)<br>0 | 5 / 10 (50.00%)<br>7  | 2 / 8 (25.00%)<br>2 |
| Blood bilirubin increased<br>subjects affected / exposed<br>occurrences (all)            | 0 / 3 (0.00%)<br>0 | 2 / 10 (20.00%)<br>5  | 2 / 8 (25.00%)<br>2 |
| Blood creatinine increased<br>subjects affected / exposed<br>occurrences (all)           | 0 / 3 (0.00%)<br>0 | 1 / 10 (10.00%)<br>1  | 1 / 8 (12.50%)<br>1 |
| Electrocardiogram QT prolonged<br>subjects affected / exposed<br>occurrences (all)       | 0 / 3 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0   | 1 / 8 (12.50%)<br>1 |
| Gamma-glutamyltransferase increased<br>subjects affected / exposed<br>occurrences (all)  | 0 / 3 (0.00%)<br>0 | 1 / 10 (10.00%)<br>1  | 1 / 8 (12.50%)<br>1 |
| Lymphocyte count decreased<br>subjects affected / exposed<br>occurrences (all)           | 0 / 3 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0   | 1 / 8 (12.50%)<br>2 |
| Platelet count decreased<br>subjects affected / exposed<br>occurrences (all)             | 0 / 3 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0   | 1 / 8 (12.50%)<br>3 |
| Weight decreased                                                                         |                    |                       |                     |

|                                                                                   |                    |                      |                     |
|-----------------------------------------------------------------------------------|--------------------|----------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                                  | 0 / 3 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Blood sodium increased<br>subjects affected / exposed<br>occurrences (all)        | 0 / 3 (0.00%)<br>0 | 1 / 10 (10.00%)<br>1 | 0 / 8 (0.00%)<br>0  |
| Liver function test increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 3 (0.00%)<br>0 | 1 / 10 (10.00%)<br>1 | 0 / 8 (0.00%)<br>0  |
| Injury, poisoning and procedural complications                                    |                    |                      |                     |
| Fall<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 3 (0.00%)<br>0 | 1 / 10 (10.00%)<br>1 | 1 / 8 (12.50%)<br>1 |
| Head injury<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 3 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 |
| Cardiac disorders                                                                 |                    |                      |                     |
| Atrial fibrillation<br>subjects affected / exposed<br>occurrences (all)           | 0 / 3 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 |
| Mitral valve incompetence<br>subjects affected / exposed<br>occurrences (all)     | 0 / 3 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 |
| Pericarditis<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 3 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 |
| Sinus bradycardia<br>subjects affected / exposed<br>occurrences (all)             | 0 / 3 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 |
| Tachycardia<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 3 (0.00%)<br>0 | 1 / 10 (10.00%)<br>1 | 0 / 8 (0.00%)<br>0  |
| Nervous system disorders                                                          |                    |                      |                     |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 3 (0.00%)<br>0 | 3 / 10 (30.00%)<br>4 | 0 / 8 (0.00%)<br>0  |
| Dysarthria                                                                        |                    |                      |                     |

|                                      |               |                 |                |
|--------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed          | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                    | 0             | 0               | 1              |
| Dysgeusia                            |               |                 |                |
| subjects affected / exposed          | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                    | 0             | 0               | 1              |
| Headache                             |               |                 |                |
| subjects affected / exposed          | 0 / 3 (0.00%) | 3 / 10 (30.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0             | 3               | 0              |
| Neuropathy peripheral                |               |                 |                |
| subjects affected / exposed          | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0              |
| Peripheral sensory neuropathy        |               |                 |                |
| subjects affected / exposed          | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                    | 0             | 0               | 1              |
| Horner's syndrome                    |               |                 |                |
| subjects affected / exposed          | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0             | 1               | 0              |
| Seizure                              |               |                 |                |
| subjects affected / exposed          | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0              |
| Somnolence                           |               |                 |                |
| subjects affected / exposed          | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0              |
| Blood and lymphatic system disorders |               |                 |                |
| Anaemia                              |               |                 |                |
| subjects affected / exposed          | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 2 / 8 (25.00%) |
| occurrences (all)                    | 0             | 1               | 3              |
| Lymphopenia                          |               |                 |                |
| subjects affected / exposed          | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0              |
| Thrombocytopenia                     |               |                 |                |
| subjects affected / exposed          | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                    | 0             | 0               | 0              |
| Eye disorders                        |               |                 |                |
| Blepharitis                          |               |                 |                |

|                               |               |                 |                |
|-------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0               | 0              |
| Cataract                      |               |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0               | 0              |
| Dry eye                       |               |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0               | 0              |
| Strabismus                    |               |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)             | 0             | 0               | 1              |
| Vision blurred                |               |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0               | 0              |
| Vitreous floaters             |               |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)             | 0             | 0               | 1              |
| Chalazion                     |               |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 1               | 0              |
| Eye pain                      |               |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0               | 0              |
| Lacrimation increased         |               |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 1               | 0              |
| Narrow anterior chamber angle |               |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0               | 0              |
| Swelling of eyelid            |               |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0               | 0              |
| Visual impairment             |               |                 |                |
| subjects affected / exposed   | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)             | 0             | 0               | 0              |
| Gastrointestinal disorders    |               |                 |                |

|                             |               |                 |                |
|-----------------------------|---------------|-----------------|----------------|
| Abdominal distension        |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 1 / 8 (12.50%) |
| occurrences (all)           | 0             | 2               | 1              |
| Abdominal pain              |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 3 / 10 (30.00%) | 4 / 8 (50.00%) |
| occurrences (all)           | 0             | 4               | 6              |
| Abdominal pain lower        |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 0               | 0              |
| Abdominal pain upper        |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 1 / 8 (12.50%) |
| occurrences (all)           | 0             | 2               | 1              |
| Ascites                     |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 3 / 10 (30.00%) | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 5               | 0              |
| Breath odour                |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 0               | 0              |
| Constipation                |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 4 / 10 (40.00%) | 3 / 8 (37.50%) |
| occurrences (all)           | 0             | 4               | 3              |
| Diarrhoea                   |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 8 / 10 (80.00%) | 1 / 8 (12.50%) |
| occurrences (all)           | 0             | 11              | 2              |
| Dry mouth                   |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 3 / 10 (30.00%) | 1 / 8 (12.50%) |
| occurrences (all)           | 0             | 3               | 1              |
| Dyspepsia                   |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 1               | 0              |
| Dysphagia                   |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 1 / 8 (12.50%) |
| occurrences (all)           | 0             | 1               | 1              |
| Eructation                  |               |                 |                |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)           | 0             | 0               | 0              |

|                                  |                 |                 |                |
|----------------------------------|-----------------|-----------------|----------------|
| Flatulence                       |                 |                 |                |
| subjects affected / exposed      | 0 / 3 (0.00%)   | 1 / 10 (10.00%) | 1 / 8 (12.50%) |
| occurrences (all)                | 0               | 1               | 1              |
| Gastrooesophageal reflux disease |                 |                 |                |
| subjects affected / exposed      | 0 / 3 (0.00%)   | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                | 0               | 1               | 0              |
| Haemorrhoids                     |                 |                 |                |
| subjects affected / exposed      | 0 / 3 (0.00%)   | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                | 0               | 0               | 0              |
| Nausea                           |                 |                 |                |
| subjects affected / exposed      | 3 / 3 (100.00%) | 7 / 10 (70.00%) | 3 / 8 (37.50%) |
| occurrences (all)                | 4               | 15              | 4              |
| Rectal haemorrhage               |                 |                 |                |
| subjects affected / exposed      | 0 / 3 (0.00%)   | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                | 0               | 0               | 1              |
| Stomatitis                       |                 |                 |                |
| subjects affected / exposed      | 0 / 3 (0.00%)   | 3 / 10 (30.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                | 0               | 4               | 0              |
| Swollen tongue                   |                 |                 |                |
| subjects affected / exposed      | 0 / 3 (0.00%)   | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                | 0               | 0               | 1              |
| Vomiting                         |                 |                 |                |
| subjects affected / exposed      | 2 / 3 (66.67%)  | 4 / 10 (40.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                | 2               | 7               | 0              |
| Abdominal discomfort             |                 |                 |                |
| subjects affected / exposed      | 0 / 3 (0.00%)   | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                | 0               | 0               | 0              |
| Impaired gastric emptying        |                 |                 |                |
| subjects affected / exposed      | 0 / 3 (0.00%)   | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                | 0               | 0               | 0              |
| Retching                         |                 |                 |                |
| subjects affected / exposed      | 0 / 3 (0.00%)   | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                | 0               | 1               | 0              |
| Umbilical hernia                 |                 |                 |                |
| subjects affected / exposed      | 0 / 3 (0.00%)   | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                | 0               | 0               | 0              |

|                                        |                |                 |                |
|----------------------------------------|----------------|-----------------|----------------|
| Hepatobiliary disorders                |                |                 |                |
| Hyperbilirubinaemia                    |                |                 |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0              | 3               | 0              |
| Skin and subcutaneous tissue disorders |                |                 |                |
| Dry skin                               |                |                 |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0              | 1               | 0              |
| Pruritus                               |                |                 |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0              | 1               | 0              |
| Rash                                   |                |                 |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0              |
| Rash papular                           |                |                 |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0              |
| Skin odour abnormal                    |                |                 |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0              |
| Night sweats                           |                |                 |                |
| subjects affected / exposed            | 1 / 3 (33.33%) | 2 / 10 (20.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 1              | 2               | 0              |
| Rash macular                           |                |                 |                |
| subjects affected / exposed            | 1 / 3 (33.33%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                      | 1              | 0               | 0              |
| Renal and urinary disorders            |                |                 |                |
| Acute kidney injury                    |                |                 |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                      | 0              | 1               | 0              |
| Chromaturia                            |                |                 |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                      | 0              | 0               | 1              |
| Nocturia                               |                |                 |                |
| subjects affected / exposed            | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                      | 0              | 0               | 1              |
| Proteinuria                            |                |                 |                |

|                                                 |                |                 |                |
|-------------------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Urine odour abnormal                            |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Urinary retention                               |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 1               | 0              |
| Endocrine disorders                             |                |                 |                |
| Hypothyroidism                                  |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Musculoskeletal and connective tissue disorders |                |                 |                |
| Arthralgia                                      |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0              |
| Back pain                                       |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 1 / 8 (12.50%) |
| occurrences (all)                               | 0              | 2               | 1              |
| Flank pain                                      |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 2 / 8 (25.00%) |
| occurrences (all)                               | 0              | 4               | 3              |
| Muscle spasms                                   |                |                 |                |
| subjects affected / exposed                     | 1 / 3 (33.33%) | 3 / 10 (30.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                               | 1              | 5               | 0              |
| Muscular weakness                               |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 1               | 0              |
| Musculoskeletal chest pain                      |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                               | 0              | 1               | 0              |
| Musculoskeletal pain                            |                |                 |                |
| subjects affected / exposed                     | 0 / 3 (0.00%)  | 2 / 10 (20.00%) | 1 / 8 (12.50%) |
| occurrences (all)                               | 0              | 2               | 1              |
| Myalgia                                         |                |                 |                |

|                                   |               |                 |                |
|-----------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed       | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 1               | 0              |
| Pain in extremity                 |               |                 |                |
| subjects affected / exposed       | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Groin pain                        |               |                 |                |
| subjects affected / exposed       | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 1               | 0              |
| Musculoskeletal discomfort        |               |                 |                |
| subjects affected / exposed       | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Neck pain                         |               |                 |                |
| subjects affected / exposed       | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Infections and infestations       |               |                 |                |
| Nasopharyngitis                   |               |                 |                |
| subjects affected / exposed       | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Pneumonia                         |               |                 |                |
| subjects affected / exposed       | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 1 / 8 (12.50%) |
| occurrences (all)                 | 0             | 0               | 1              |
| Upper respiratory tract infection |               |                 |                |
| subjects affected / exposed       | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Urinary tract infection           |               |                 |                |
| subjects affected / exposed       | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 1               | 0              |
| Conjunctivitis                    |               |                 |                |
| subjects affected / exposed       | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Cystitis                          |               |                 |                |
| subjects affected / exposed       | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 1               | 0              |
| Lower respiratory tract infection |               |                 |                |
| subjects affected / exposed       | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |

|                                                                                 |                     |                      |                     |
|---------------------------------------------------------------------------------|---------------------|----------------------|---------------------|
| Oral herpes<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 3 (0.00%)<br>0  | 1 / 10 (10.00%)<br>1 | 0 / 8 (0.00%)<br>0  |
| Respiratory tract infection<br>subjects affected / exposed<br>occurrences (all) | 0 / 3 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Metabolism and nutrition disorders                                              |                     |                      |                     |
| Decreased appetite<br>subjects affected / exposed<br>occurrences (all)          | 1 / 3 (33.33%)<br>1 | 5 / 10 (50.00%)<br>8 | 2 / 8 (25.00%)<br>2 |
| Dehydration<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 3 (0.00%)<br>0  | 1 / 10 (10.00%)<br>1 | 0 / 8 (0.00%)<br>0  |
| Hyperglycaemia<br>subjects affected / exposed<br>occurrences (all)              | 1 / 3 (33.33%)<br>3 | 0 / 10 (0.00%)<br>0  | 2 / 8 (25.00%)<br>3 |
| Hyperuricaemia<br>subjects affected / exposed<br>occurrences (all)              | 0 / 3 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Hypoalbuminaemia<br>subjects affected / exposed<br>occurrences (all)            | 0 / 3 (0.00%)<br>0  | 1 / 10 (10.00%)<br>1 | 0 / 8 (0.00%)<br>0  |
| Hypokalaemia<br>subjects affected / exposed<br>occurrences (all)                | 0 / 3 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Hypomagnesaemia<br>subjects affected / exposed<br>occurrences (all)             | 1 / 3 (33.33%)<br>1 | 0 / 10 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Hyponatraemia<br>subjects affected / exposed<br>occurrences (all)               | 1 / 3 (33.33%)<br>1 | 0 / 10 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Hypophosphataemia<br>subjects affected / exposed<br>occurrences (all)           | 1 / 3 (33.33%)<br>1 | 2 / 10 (20.00%)<br>2 | 0 / 8 (0.00%)<br>0  |
| Increased appetite                                                              |                     |                      |                     |

|                             |               |                 |               |
|-----------------------------|---------------|-----------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 10 (0.00%)  | 0 / 8 (0.00%) |
| occurrences (all)           | 0             | 0               | 0             |
| Hypoglycaemia               |               |                 |               |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 10 (10.00%) | 0 / 8 (0.00%) |
| occurrences (all)           | 0             | 1               | 0             |

| <b>Non-serious adverse events</b>                                   | BMS 1.2MG/KG Q3W | BMS 0.6MG/KG QW | BMS 0.8MG/KG Q3W+N |
|---------------------------------------------------------------------|------------------|-----------------|--------------------|
| Total subjects affected by non-serious adverse events               |                  |                 |                    |
| subjects affected / exposed                                         | 58 / 59 (98.31%) | 4 / 4 (100.00%) | 27 / 30 (90.00%)   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                  |                 |                    |
| Tumour pain                                                         |                  |                 |                    |
| subjects affected / exposed                                         | 1 / 59 (1.69%)   | 0 / 4 (0.00%)   | 0 / 30 (0.00%)     |
| occurrences (all)                                                   | 1                | 0               | 0                  |
| Vascular disorders                                                  |                  |                 |                    |
| Hypertension                                                        |                  |                 |                    |
| subjects affected / exposed                                         | 2 / 59 (3.39%)   | 0 / 4 (0.00%)   | 2 / 30 (6.67%)     |
| occurrences (all)                                                   | 2                | 0               | 2                  |
| Systolic hypertension                                               |                  |                 |                    |
| subjects affected / exposed                                         | 0 / 59 (0.00%)   | 0 / 4 (0.00%)   | 0 / 30 (0.00%)     |
| occurrences (all)                                                   | 0                | 0               | 0                  |
| Flushing                                                            |                  |                 |                    |
| subjects affected / exposed                                         | 1 / 59 (1.69%)   | 0 / 4 (0.00%)   | 0 / 30 (0.00%)     |
| occurrences (all)                                                   | 1                | 0               | 0                  |
| Hypotension                                                         |                  |                 |                    |
| subjects affected / exposed                                         | 1 / 59 (1.69%)   | 0 / 4 (0.00%)   | 0 / 30 (0.00%)     |
| occurrences (all)                                                   | 1                | 0               | 0                  |
| General disorders and administration site conditions                |                  |                 |                    |
| Asthenia                                                            |                  |                 |                    |
| subjects affected / exposed                                         | 0 / 59 (0.00%)   | 1 / 4 (25.00%)  | 0 / 30 (0.00%)     |
| occurrences (all)                                                   | 0                | 1               | 0                  |
| Chest discomfort                                                    |                  |                 |                    |
| subjects affected / exposed                                         | 0 / 59 (0.00%)   | 0 / 4 (0.00%)   | 0 / 30 (0.00%)     |
| occurrences (all)                                                   | 0                | 0               | 0                  |
| Chest pain                                                          |                  |                 |                    |
| subjects affected / exposed                                         | 10 / 59 (16.95%) | 0 / 4 (0.00%)   | 1 / 30 (3.33%)     |
| occurrences (all)                                                   | 12               | 0               | 3                  |

|                                          |                  |                |                  |
|------------------------------------------|------------------|----------------|------------------|
| Chills                                   |                  |                |                  |
| subjects affected / exposed              | 0 / 59 (0.00%)   | 0 / 4 (0.00%)  | 3 / 30 (10.00%)  |
| occurrences (all)                        | 0                | 0              | 4                |
| Fatigue                                  |                  |                |                  |
| subjects affected / exposed              | 32 / 59 (54.24%) | 3 / 4 (75.00%) | 15 / 30 (50.00%) |
| occurrences (all)                        | 60               | 7              | 21               |
| Influenza like illness                   |                  |                |                  |
| subjects affected / exposed              | 2 / 59 (3.39%)   | 1 / 4 (25.00%) | 2 / 30 (6.67%)   |
| occurrences (all)                        | 3                | 1              | 2                |
| Malaise                                  |                  |                |                  |
| subjects affected / exposed              | 1 / 59 (1.69%)   | 2 / 4 (50.00%) | 1 / 30 (3.33%)   |
| occurrences (all)                        | 1                | 2              | 1                |
| Non-cardiac chest pain                   |                  |                |                  |
| subjects affected / exposed              | 5 / 59 (8.47%)   | 1 / 4 (25.00%) | 5 / 30 (16.67%)  |
| occurrences (all)                        | 7                | 1              | 7                |
| Oedema peripheral                        |                  |                |                  |
| subjects affected / exposed              | 9 / 59 (15.25%)  | 0 / 4 (0.00%)  | 2 / 30 (6.67%)   |
| occurrences (all)                        | 11               | 0              | 4                |
| Pyrexia                                  |                  |                |                  |
| subjects affected / exposed              | 14 / 59 (23.73%) | 2 / 4 (50.00%) | 3 / 30 (10.00%)  |
| occurrences (all)                        | 25               | 4              | 5                |
| Early satiety                            |                  |                |                  |
| subjects affected / exposed              | 0 / 59 (0.00%)   | 0 / 4 (0.00%)  | 0 / 30 (0.00%)   |
| occurrences (all)                        | 0                | 0              | 0                |
| Mucosal inflammation                     |                  |                |                  |
| subjects affected / exposed              | 0 / 59 (0.00%)   | 0 / 4 (0.00%)  | 0 / 30 (0.00%)   |
| occurrences (all)                        | 0                | 0              | 0                |
| Pain                                     |                  |                |                  |
| subjects affected / exposed              | 2 / 59 (3.39%)   | 0 / 4 (0.00%)  | 0 / 30 (0.00%)   |
| occurrences (all)                        | 3                | 0              | 0                |
| Immune system disorders                  |                  |                |                  |
| Hypersensitivity                         |                  |                |                  |
| subjects affected / exposed              | 0 / 59 (0.00%)   | 0 / 4 (0.00%)  | 0 / 30 (0.00%)   |
| occurrences (all)                        | 0                | 0              | 0                |
| Reproductive system and breast disorders |                  |                |                  |

|                                                                         |                        |                     |                      |
|-------------------------------------------------------------------------|------------------------|---------------------|----------------------|
| Testicular pain<br>subjects affected / exposed<br>occurrences (all)     | 0 / 59 (0.00%)<br>0    | 1 / 4 (25.00%)<br>1 | 0 / 30 (0.00%)<br>0  |
| Pelvic pain<br>subjects affected / exposed<br>occurrences (all)         | 0 / 59 (0.00%)<br>0    | 0 / 4 (0.00%)<br>0  | 0 / 30 (0.00%)<br>0  |
| Respiratory, thoracic and mediastinal disorders                         |                        |                     |                      |
| Cough<br>subjects affected / exposed<br>occurrences (all)               | 13 / 59 (22.03%)<br>18 | 0 / 4 (0.00%)<br>0  | 5 / 30 (16.67%)<br>5 |
| Dysphonia<br>subjects affected / exposed<br>occurrences (all)           | 1 / 59 (1.69%)<br>1    | 1 / 4 (25.00%)<br>1 | 1 / 30 (3.33%)<br>1  |
| Dyspnoea<br>subjects affected / exposed<br>occurrences (all)            | 20 / 59 (33.90%)<br>31 | 1 / 4 (25.00%)<br>1 | 5 / 30 (16.67%)<br>6 |
| Dyspnoea exertional<br>subjects affected / exposed<br>occurrences (all) | 0 / 59 (0.00%)<br>0    | 0 / 4 (0.00%)<br>0  | 0 / 30 (0.00%)<br>0  |
| Epistaxis<br>subjects affected / exposed<br>occurrences (all)           | 3 / 59 (5.08%)<br>3    | 0 / 4 (0.00%)<br>0  | 2 / 30 (6.67%)<br>2  |
| Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)  | 1 / 59 (1.69%)<br>2    | 1 / 4 (25.00%)<br>1 | 1 / 30 (3.33%)<br>1  |
| Pleural effusion<br>subjects affected / exposed<br>occurrences (all)    | 4 / 59 (6.78%)<br>4    | 0 / 4 (0.00%)<br>0  | 3 / 30 (10.00%)<br>3 |
| Pleuritic pain<br>subjects affected / exposed<br>occurrences (all)      | 7 / 59 (11.86%)<br>10  | 1 / 4 (25.00%)<br>2 | 3 / 30 (10.00%)<br>4 |
| Productive cough<br>subjects affected / exposed<br>occurrences (all)    | 7 / 59 (11.86%)<br>9   | 0 / 4 (0.00%)<br>0  | 1 / 30 (3.33%)<br>1  |
| Rales                                                                   |                        |                     |                      |

|                             |                |                |                 |
|-----------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 59 (0.00%) | 1 / 4 (25.00%) | 0 / 30 (0.00%)  |
| occurrences (all)           | 0              | 3              | 0               |
| Throat irritation           |                |                |                 |
| subjects affected / exposed | 0 / 59 (0.00%) | 1 / 4 (25.00%) | 1 / 30 (3.33%)  |
| occurrences (all)           | 0              | 1              | 1               |
| Haemoptysis                 |                |                |                 |
| subjects affected / exposed | 1 / 59 (1.69%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)           | 1              | 0              | 0               |
| Hiccups                     |                |                |                 |
| subjects affected / exposed | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 1 / 30 (3.33%)  |
| occurrences (all)           | 0              | 0              | 1               |
| Hypoxia                     |                |                |                 |
| subjects affected / exposed | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 1 / 30 (3.33%)  |
| occurrences (all)           | 0              | 0              | 1               |
| Nasal congestion            |                |                |                 |
| subjects affected / exposed | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Psychiatric disorders       |                |                |                 |
| Abnormal dreams             |                |                |                 |
| subjects affected / exposed | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Anxiety                     |                |                |                 |
| subjects affected / exposed | 3 / 59 (5.08%) | 1 / 4 (25.00%) | 1 / 30 (3.33%)  |
| occurrences (all)           | 3              | 1              | 1               |
| Confusional state           |                |                |                 |
| subjects affected / exposed | 2 / 59 (3.39%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)           | 2              | 0              | 0               |
| Delirium                    |                |                |                 |
| subjects affected / exposed | 0 / 59 (0.00%) | 1 / 4 (25.00%) | 0 / 30 (0.00%)  |
| occurrences (all)           | 0              | 1              | 0               |
| Hallucination, auditory     |                |                |                 |
| subjects affected / exposed | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Insomnia                    |                |                |                 |
| subjects affected / exposed | 4 / 59 (6.78%) | 0 / 4 (0.00%)  | 6 / 30 (20.00%) |
| occurrences (all)           | 4              | 0              | 6               |

|                                                                                          |                         |                      |                        |
|------------------------------------------------------------------------------------------|-------------------------|----------------------|------------------------|
| Depression<br>subjects affected / exposed<br>occurrences (all)                           | 0 / 59 (0.00%)<br>0     | 0 / 4 (0.00%)<br>0   | 0 / 30 (0.00%)<br>0    |
| Hallucination<br>subjects affected / exposed<br>occurrences (all)                        | 1 / 59 (1.69%)<br>1     | 0 / 4 (0.00%)<br>0   | 0 / 30 (0.00%)<br>0    |
| Investigations                                                                           |                         |                      |                        |
| Alanine aminotransferase increased<br>subjects affected / exposed<br>occurrences (all)   | 33 / 59 (55.93%)<br>94  | 3 / 4 (75.00%)<br>12 | 10 / 30 (33.33%)<br>24 |
| Aspartate aminotransferase increased<br>subjects affected / exposed<br>occurrences (all) | 35 / 59 (59.32%)<br>111 | 3 / 4 (75.00%)<br>7  | 12 / 30 (40.00%)<br>31 |
| Blood alkaline phosphatase increased<br>subjects affected / exposed<br>occurrences (all) | 18 / 59 (30.51%)<br>31  | 2 / 4 (50.00%)<br>3  | 5 / 30 (16.67%)<br>11  |
| Blood bilirubin increased<br>subjects affected / exposed<br>occurrences (all)            | 8 / 59 (13.56%)<br>15   | 2 / 4 (50.00%)<br>2  | 2 / 30 (6.67%)<br>5    |
| Blood creatinine increased<br>subjects affected / exposed<br>occurrences (all)           | 0 / 59 (0.00%)<br>0     | 1 / 4 (25.00%)<br>1  | 1 / 30 (3.33%)<br>2    |
| Electrocardiogram QT prolonged<br>subjects affected / exposed<br>occurrences (all)       | 0 / 59 (0.00%)<br>0     | 0 / 4 (0.00%)<br>0   | 0 / 30 (0.00%)<br>0    |
| Gamma-glutamyltransferase increased<br>subjects affected / exposed<br>occurrences (all)  | 4 / 59 (6.78%)<br>7     | 0 / 4 (0.00%)<br>0   | 0 / 30 (0.00%)<br>0    |
| Lymphocyte count decreased<br>subjects affected / exposed<br>occurrences (all)           | 1 / 59 (1.69%)<br>1     | 0 / 4 (0.00%)<br>0   | 1 / 30 (3.33%)<br>3    |
| Platelet count decreased<br>subjects affected / exposed<br>occurrences (all)             | 3 / 59 (5.08%)<br>5     | 0 / 4 (0.00%)<br>0   | 0 / 30 (0.00%)<br>0    |
| Weight decreased                                                                         |                         |                      |                        |

|                                                                                   |                     |                     |                      |
|-----------------------------------------------------------------------------------|---------------------|---------------------|----------------------|
| subjects affected / exposed<br>occurrences (all)                                  | 5 / 59 (8.47%)<br>8 | 0 / 4 (0.00%)<br>0  | 5 / 30 (16.67%)<br>8 |
| Blood sodium increased<br>subjects affected / exposed<br>occurrences (all)        | 0 / 59 (0.00%)<br>0 | 0 / 4 (0.00%)<br>0  | 0 / 30 (0.00%)<br>0  |
| Liver function test increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 59 (0.00%)<br>0 | 0 / 4 (0.00%)<br>0  | 1 / 30 (3.33%)<br>1  |
| Injury, poisoning and procedural complications                                    |                     |                     |                      |
| Fall<br>subjects affected / exposed<br>occurrences (all)                          | 1 / 59 (1.69%)<br>1 | 0 / 4 (0.00%)<br>0  | 1 / 30 (3.33%)<br>1  |
| Head injury<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 59 (0.00%)<br>0 | 0 / 4 (0.00%)<br>0  | 0 / 30 (0.00%)<br>0  |
| Cardiac disorders                                                                 |                     |                     |                      |
| Atrial fibrillation<br>subjects affected / exposed<br>occurrences (all)           | 1 / 59 (1.69%)<br>2 | 0 / 4 (0.00%)<br>0  | 0 / 30 (0.00%)<br>0  |
| Mitral valve incompetence<br>subjects affected / exposed<br>occurrences (all)     | 0 / 59 (0.00%)<br>0 | 0 / 4 (0.00%)<br>0  | 0 / 30 (0.00%)<br>0  |
| Pericarditis<br>subjects affected / exposed<br>occurrences (all)                  | 1 / 59 (1.69%)<br>1 | 0 / 4 (0.00%)<br>0  | 0 / 30 (0.00%)<br>0  |
| Sinus bradycardia<br>subjects affected / exposed<br>occurrences (all)             | 1 / 59 (1.69%)<br>1 | 0 / 4 (0.00%)<br>0  | 0 / 30 (0.00%)<br>0  |
| Tachycardia<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 59 (0.00%)<br>0 | 0 / 4 (0.00%)<br>0  | 2 / 30 (6.67%)<br>2  |
| Nervous system disorders                                                          |                     |                     |                      |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                     | 5 / 59 (8.47%)<br>8 | 1 / 4 (25.00%)<br>1 | 1 / 30 (3.33%)<br>1  |
| Dysarthria                                                                        |                     |                     |                      |

|                                      |                 |                |                 |
|--------------------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed          | 0 / 59 (0.00%)  | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                    | 0               | 0              | 0               |
| Dysgeusia                            |                 |                |                 |
| subjects affected / exposed          | 6 / 59 (10.17%) | 2 / 4 (50.00%) | 4 / 30 (13.33%) |
| occurrences (all)                    | 6               | 2              | 7               |
| Headache                             |                 |                |                 |
| subjects affected / exposed          | 6 / 59 (10.17%) | 1 / 4 (25.00%) | 4 / 30 (13.33%) |
| occurrences (all)                    | 8               | 2              | 4               |
| Neuropathy peripheral                |                 |                |                 |
| subjects affected / exposed          | 4 / 59 (6.78%)  | 1 / 4 (25.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                    | 9               | 1              | 0               |
| Peripheral sensory neuropathy        |                 |                |                 |
| subjects affected / exposed          | 3 / 59 (5.08%)  | 0 / 4 (0.00%)  | 1 / 30 (3.33%)  |
| occurrences (all)                    | 5               | 0              | 1               |
| Horner's syndrome                    |                 |                |                 |
| subjects affected / exposed          | 0 / 59 (0.00%)  | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                    | 0               | 0              | 0               |
| Seizure                              |                 |                |                 |
| subjects affected / exposed          | 0 / 59 (0.00%)  | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                    | 0               | 0              | 0               |
| Somnolence                           |                 |                |                 |
| subjects affected / exposed          | 0 / 59 (0.00%)  | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                    | 0               | 0              | 0               |
| Blood and lymphatic system disorders |                 |                |                 |
| Anaemia                              |                 |                |                 |
| subjects affected / exposed          | 6 / 59 (10.17%) | 1 / 4 (25.00%) | 2 / 30 (6.67%)  |
| occurrences (all)                    | 7               | 4              | 3               |
| Lymphopenia                          |                 |                |                 |
| subjects affected / exposed          | 0 / 59 (0.00%)  | 1 / 4 (25.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                    | 0               | 1              | 0               |
| Thrombocytopenia                     |                 |                |                 |
| subjects affected / exposed          | 3 / 59 (5.08%)  | 1 / 4 (25.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                    | 3               | 2              | 0               |
| Eye disorders                        |                 |                |                 |
| Blepharitis                          |                 |                |                 |

|                               |                 |                |                 |
|-------------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed   | 2 / 59 (3.39%)  | 1 / 4 (25.00%) | 0 / 30 (0.00%)  |
| occurrences (all)             | 2               | 1              | 0               |
| Cataract                      |                 |                |                 |
| subjects affected / exposed   | 3 / 59 (5.08%)  | 0 / 4 (0.00%)  | 3 / 30 (10.00%) |
| occurrences (all)             | 4               | 0              | 4               |
| Dry eye                       |                 |                |                 |
| subjects affected / exposed   | 5 / 59 (8.47%)  | 0 / 4 (0.00%)  | 2 / 30 (6.67%)  |
| occurrences (all)             | 6               | 0              | 2               |
| Strabismus                    |                 |                |                 |
| subjects affected / exposed   | 0 / 59 (0.00%)  | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)             | 0               | 0              | 0               |
| Vision blurred                |                 |                |                 |
| subjects affected / exposed   | 6 / 59 (10.17%) | 0 / 4 (0.00%)  | 3 / 30 (10.00%) |
| occurrences (all)             | 8               | 0              | 3               |
| Vitreous floaters             |                 |                |                 |
| subjects affected / exposed   | 0 / 59 (0.00%)  | 0 / 4 (0.00%)  | 1 / 30 (3.33%)  |
| occurrences (all)             | 0               | 0              | 1               |
| Chalazion                     |                 |                |                 |
| subjects affected / exposed   | 0 / 59 (0.00%)  | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)             | 0               | 0              | 0               |
| Eye pain                      |                 |                |                 |
| subjects affected / exposed   | 0 / 59 (0.00%)  | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)             | 0               | 0              | 0               |
| Lacrimation increased         |                 |                |                 |
| subjects affected / exposed   | 1 / 59 (1.69%)  | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)             | 1               | 0              | 0               |
| Narrow anterior chamber angle |                 |                |                 |
| subjects affected / exposed   | 0 / 59 (0.00%)  | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)             | 0               | 0              | 0               |
| Swelling of eyelid            |                 |                |                 |
| subjects affected / exposed   | 1 / 59 (1.69%)  | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)             | 1               | 0              | 0               |
| Visual impairment             |                 |                |                 |
| subjects affected / exposed   | 0 / 59 (0.00%)  | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)             | 0               | 0              | 0               |
| Gastrointestinal disorders    |                 |                |                 |

|                             |                  |                |                  |
|-----------------------------|------------------|----------------|------------------|
| Abdominal distension        |                  |                |                  |
| subjects affected / exposed | 5 / 59 (8.47%)   | 0 / 4 (0.00%)  | 2 / 30 (6.67%)   |
| occurrences (all)           | 5                | 0              | 3                |
| Abdominal pain              |                  |                |                  |
| subjects affected / exposed | 15 / 59 (25.42%) | 1 / 4 (25.00%) | 5 / 30 (16.67%)  |
| occurrences (all)           | 28               | 1              | 9                |
| Abdominal pain lower        |                  |                |                  |
| subjects affected / exposed | 2 / 59 (3.39%)   | 0 / 4 (0.00%)  | 4 / 30 (13.33%)  |
| occurrences (all)           | 4                | 0              | 4                |
| Abdominal pain upper        |                  |                |                  |
| subjects affected / exposed | 4 / 59 (6.78%)   | 0 / 4 (0.00%)  | 1 / 30 (3.33%)   |
| occurrences (all)           | 4                | 0              | 1                |
| Ascites                     |                  |                |                  |
| subjects affected / exposed | 5 / 59 (8.47%)   | 0 / 4 (0.00%)  | 6 / 30 (20.00%)  |
| occurrences (all)           | 5                | 0              | 16               |
| Breath odour                |                  |                |                  |
| subjects affected / exposed | 0 / 59 (0.00%)   | 1 / 4 (25.00%) | 0 / 30 (0.00%)   |
| occurrences (all)           | 0                | 1              | 0                |
| Constipation                |                  |                |                  |
| subjects affected / exposed | 16 / 59 (27.12%) | 1 / 4 (25.00%) | 10 / 30 (33.33%) |
| occurrences (all)           | 26               | 1              | 14               |
| Diarrhoea                   |                  |                |                  |
| subjects affected / exposed | 13 / 59 (22.03%) | 1 / 4 (25.00%) | 5 / 30 (16.67%)  |
| occurrences (all)           | 21               | 2              | 7                |
| Dry mouth                   |                  |                |                  |
| subjects affected / exposed | 5 / 59 (8.47%)   | 0 / 4 (0.00%)  | 5 / 30 (16.67%)  |
| occurrences (all)           | 6                | 0              | 5                |
| Dyspepsia                   |                  |                |                  |
| subjects affected / exposed | 5 / 59 (8.47%)   | 1 / 4 (25.00%) | 3 / 30 (10.00%)  |
| occurrences (all)           | 6                | 1              | 3                |
| Dysphagia                   |                  |                |                  |
| subjects affected / exposed | 0 / 59 (0.00%)   | 1 / 4 (25.00%) | 1 / 30 (3.33%)   |
| occurrences (all)           | 0                | 1              | 1                |
| Eructation                  |                  |                |                  |
| subjects affected / exposed | 1 / 59 (1.69%)   | 0 / 4 (0.00%)  | 2 / 30 (6.67%)   |
| occurrences (all)           | 2                | 0              | 2                |

|                                  |                  |                |                  |
|----------------------------------|------------------|----------------|------------------|
| Flatulence                       |                  |                |                  |
| subjects affected / exposed      | 1 / 59 (1.69%)   | 0 / 4 (0.00%)  | 0 / 30 (0.00%)   |
| occurrences (all)                | 2                | 0              | 0                |
| Gastrooesophageal reflux disease |                  |                |                  |
| subjects affected / exposed      | 3 / 59 (5.08%)   | 0 / 4 (0.00%)  | 2 / 30 (6.67%)   |
| occurrences (all)                | 4                | 0              | 3                |
| Haemorrhoids                     |                  |                |                  |
| subjects affected / exposed      | 1 / 59 (1.69%)   | 0 / 4 (0.00%)  | 2 / 30 (6.67%)   |
| occurrences (all)                | 1                | 0              | 2                |
| Nausea                           |                  |                |                  |
| subjects affected / exposed      | 30 / 59 (50.85%) | 1 / 4 (25.00%) | 13 / 30 (43.33%) |
| occurrences (all)                | 55               | 1              | 24               |
| Rectal haemorrhage               |                  |                |                  |
| subjects affected / exposed      | 0 / 59 (0.00%)   | 0 / 4 (0.00%)  | 0 / 30 (0.00%)   |
| occurrences (all)                | 0                | 0              | 0                |
| Stomatitis                       |                  |                |                  |
| subjects affected / exposed      | 1 / 59 (1.69%)   | 0 / 4 (0.00%)  | 1 / 30 (3.33%)   |
| occurrences (all)                | 1                | 0              | 2                |
| Swollen tongue                   |                  |                |                  |
| subjects affected / exposed      | 0 / 59 (0.00%)   | 0 / 4 (0.00%)  | 0 / 30 (0.00%)   |
| occurrences (all)                | 0                | 0              | 0                |
| Vomiting                         |                  |                |                  |
| subjects affected / exposed      | 17 / 59 (28.81%) | 1 / 4 (25.00%) | 9 / 30 (30.00%)  |
| occurrences (all)                | 35               | 1              | 11               |
| Abdominal discomfort             |                  |                |                  |
| subjects affected / exposed      | 0 / 59 (0.00%)   | 0 / 4 (0.00%)  | 0 / 30 (0.00%)   |
| occurrences (all)                | 0                | 0              | 0                |
| Impaired gastric emptying        |                  |                |                  |
| subjects affected / exposed      | 1 / 59 (1.69%)   | 0 / 4 (0.00%)  | 0 / 30 (0.00%)   |
| occurrences (all)                | 1                | 0              | 0                |
| Retching                         |                  |                |                  |
| subjects affected / exposed      | 0 / 59 (0.00%)   | 0 / 4 (0.00%)  | 0 / 30 (0.00%)   |
| occurrences (all)                | 0                | 0              | 0                |
| Umbilical hernia                 |                  |                |                  |
| subjects affected / exposed      | 1 / 59 (1.69%)   | 0 / 4 (0.00%)  | 0 / 30 (0.00%)   |
| occurrences (all)                | 1                | 0              | 0                |

|                                        |                |                |                 |
|----------------------------------------|----------------|----------------|-----------------|
| Hepatobiliary disorders                |                |                |                 |
| Hyperbilirubinaemia                    |                |                |                 |
| subjects affected / exposed            | 1 / 59 (1.69%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                      | 1              | 0              | 0               |
| Skin and subcutaneous tissue disorders |                |                |                 |
| Dry skin                               |                |                |                 |
| subjects affected / exposed            | 1 / 59 (1.69%) | 0 / 4 (0.00%)  | 3 / 30 (10.00%) |
| occurrences (all)                      | 1              | 0              | 3               |
| Pruritus                               |                |                |                 |
| subjects affected / exposed            | 2 / 59 (3.39%) | 0 / 4 (0.00%)  | 6 / 30 (20.00%) |
| occurrences (all)                      | 2              | 0              | 10              |
| Rash                                   |                |                |                 |
| subjects affected / exposed            | 4 / 59 (6.78%) | 1 / 4 (25.00%) | 4 / 30 (13.33%) |
| occurrences (all)                      | 6              | 2              | 5               |
| Rash papular                           |                |                |                 |
| subjects affected / exposed            | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 3 / 30 (10.00%) |
| occurrences (all)                      | 0              | 0              | 4               |
| Skin odour abnormal                    |                |                |                 |
| subjects affected / exposed            | 0 / 59 (0.00%) | 1 / 4 (25.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                      | 0              | 2              | 0               |
| Night sweats                           |                |                |                 |
| subjects affected / exposed            | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 1 / 30 (3.33%)  |
| occurrences (all)                      | 0              | 0              | 4               |
| Rash macular                           |                |                |                 |
| subjects affected / exposed            | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 1 / 30 (3.33%)  |
| occurrences (all)                      | 0              | 0              | 1               |
| Renal and urinary disorders            |                |                |                 |
| Acute kidney injury                    |                |                |                 |
| subjects affected / exposed            | 1 / 59 (1.69%) | 1 / 4 (25.00%) | 1 / 30 (3.33%)  |
| occurrences (all)                      | 1              | 1              | 1               |
| Chromaturia                            |                |                |                 |
| subjects affected / exposed            | 1 / 59 (1.69%) | 1 / 4 (25.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                      | 1              | 2              | 0               |
| Nocturia                               |                |                |                 |
| subjects affected / exposed            | 1 / 59 (1.69%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                      | 1              | 0              | 0               |
| Proteinuria                            |                |                |                 |

|                                                                                           |                        |                     |                      |
|-------------------------------------------------------------------------------------------|------------------------|---------------------|----------------------|
| subjects affected / exposed<br>occurrences (all)                                          | 1 / 59 (1.69%)<br>1    | 1 / 4 (25.00%)<br>1 | 0 / 30 (0.00%)<br>0  |
| Urine odour abnormal<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 59 (0.00%)<br>0    | 1 / 4 (25.00%)<br>3 | 0 / 30 (0.00%)<br>0  |
| Urinary retention<br>subjects affected / exposed<br>occurrences (all)                     | 1 / 59 (1.69%)<br>1    | 0 / 4 (0.00%)<br>0  | 0 / 30 (0.00%)<br>0  |
| Endocrine disorders<br>Hypothyroidism<br>subjects affected / exposed<br>occurrences (all) | 1 / 59 (1.69%)<br>1    | 0 / 4 (0.00%)<br>0  | 2 / 30 (6.67%)<br>2  |
| Musculoskeletal and connective tissue disorders                                           |                        |                     |                      |
| Arthralgia<br>subjects affected / exposed<br>occurrences (all)                            | 2 / 59 (3.39%)<br>2    | 0 / 4 (0.00%)<br>0  | 4 / 30 (13.33%)<br>6 |
| Back pain<br>subjects affected / exposed<br>occurrences (all)                             | 10 / 59 (16.95%)<br>11 | 1 / 4 (25.00%)<br>1 | 2 / 30 (6.67%)<br>2  |
| Flank pain<br>subjects affected / exposed<br>occurrences (all)                            | 3 / 59 (5.08%)<br>6    | 1 / 4 (25.00%)<br>5 | 3 / 30 (10.00%)<br>7 |
| Muscle spasms<br>subjects affected / exposed<br>occurrences (all)                         | 5 / 59 (8.47%)<br>9    | 0 / 4 (0.00%)<br>0  | 2 / 30 (6.67%)<br>3  |
| Muscular weakness<br>subjects affected / exposed<br>occurrences (all)                     | 2 / 59 (3.39%)<br>3    | 0 / 4 (0.00%)<br>0  | 2 / 30 (6.67%)<br>2  |
| Musculoskeletal chest pain<br>subjects affected / exposed<br>occurrences (all)            | 4 / 59 (6.78%)<br>4    | 1 / 4 (25.00%)<br>1 | 4 / 30 (13.33%)<br>8 |
| Musculoskeletal pain<br>subjects affected / exposed<br>occurrences (all)                  | 7 / 59 (11.86%)<br>11  | 2 / 4 (50.00%)<br>4 | 3 / 30 (10.00%)<br>5 |
| Myalgia                                                                                   |                        |                     |                      |

|                                   |                |                |                 |
|-----------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed       | 3 / 59 (5.08%) | 0 / 4 (0.00%)  | 2 / 30 (6.67%)  |
| occurrences (all)                 | 5              | 0              | 2               |
| Pain in extremity                 |                |                |                 |
| subjects affected / exposed       | 4 / 59 (6.78%) | 1 / 4 (25.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                 | 4              | 1              | 0               |
| Groin pain                        |                |                |                 |
| subjects affected / exposed       | 2 / 59 (3.39%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                 | 2              | 0              | 0               |
| Musculoskeletal discomfort        |                |                |                 |
| subjects affected / exposed       | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                 | 0              | 0              | 0               |
| Neck pain                         |                |                |                 |
| subjects affected / exposed       | 3 / 59 (5.08%) | 0 / 4 (0.00%)  | 1 / 30 (3.33%)  |
| occurrences (all)                 | 3              | 0              | 2               |
| Infections and infestations       |                |                |                 |
| Nasopharyngitis                   |                |                |                 |
| subjects affected / exposed       | 2 / 59 (3.39%) | 1 / 4 (25.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                 | 2              | 1              | 0               |
| Pneumonia                         |                |                |                 |
| subjects affected / exposed       | 3 / 59 (5.08%) | 0 / 4 (0.00%)  | 4 / 30 (13.33%) |
| occurrences (all)                 | 3              | 0              | 6               |
| Upper respiratory tract infection |                |                |                 |
| subjects affected / exposed       | 2 / 59 (3.39%) | 0 / 4 (0.00%)  | 4 / 30 (13.33%) |
| occurrences (all)                 | 2              | 0              | 4               |
| Urinary tract infection           |                |                |                 |
| subjects affected / exposed       | 3 / 59 (5.08%) | 1 / 4 (25.00%) | 2 / 30 (6.67%)  |
| occurrences (all)                 | 4              | 1              | 3               |
| Conjunctivitis                    |                |                |                 |
| subjects affected / exposed       | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                 | 0              | 0              | 0               |
| Cystitis                          |                |                |                 |
| subjects affected / exposed       | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                 | 0              | 0              | 0               |
| Lower respiratory tract infection |                |                |                 |
| subjects affected / exposed       | 0 / 59 (0.00%) | 0 / 4 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                 | 0              | 0              | 0               |

|                                                                                 |                        |                     |                        |
|---------------------------------------------------------------------------------|------------------------|---------------------|------------------------|
| Oral herpes<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 59 (1.69%)<br>5    | 0 / 4 (0.00%)<br>0  | 1 / 30 (3.33%)<br>1    |
| Respiratory tract infection<br>subjects affected / exposed<br>occurrences (all) | 1 / 59 (1.69%)<br>1    | 0 / 4 (0.00%)<br>0  | 1 / 30 (3.33%)<br>1    |
| Metabolism and nutrition disorders                                              |                        |                     |                        |
| Decreased appetite<br>subjects affected / exposed<br>occurrences (all)          | 26 / 59 (44.07%)<br>47 | 2 / 4 (50.00%)<br>2 | 11 / 30 (36.67%)<br>19 |
| Dehydration<br>subjects affected / exposed<br>occurrences (all)                 | 2 / 59 (3.39%)<br>2    | 1 / 4 (25.00%)<br>2 | 1 / 30 (3.33%)<br>1    |
| Hyperglycaemia<br>subjects affected / exposed<br>occurrences (all)              | 1 / 59 (1.69%)<br>1    | 1 / 4 (25.00%)<br>1 | 2 / 30 (6.67%)<br>2    |
| Hyperuricaemia<br>subjects affected / exposed<br>occurrences (all)              | 0 / 59 (0.00%)<br>0    | 1 / 4 (25.00%)<br>1 | 0 / 30 (0.00%)<br>0    |
| Hypoalbuminaemia<br>subjects affected / exposed<br>occurrences (all)            | 4 / 59 (6.78%)<br>4    | 0 / 4 (0.00%)<br>0  | 4 / 30 (13.33%)<br>4   |
| Hypokalaemia<br>subjects affected / exposed<br>occurrences (all)                | 6 / 59 (10.17%)<br>6   | 0 / 4 (0.00%)<br>0  | 0 / 30 (0.00%)<br>0    |
| Hypomagnesaemia<br>subjects affected / exposed<br>occurrences (all)             | 4 / 59 (6.78%)<br>4    | 1 / 4 (25.00%)<br>1 | 1 / 30 (3.33%)<br>1    |
| Hyponatraemia<br>subjects affected / exposed<br>occurrences (all)               | 2 / 59 (3.39%)<br>3    | 0 / 4 (0.00%)<br>0  | 2 / 30 (6.67%)<br>5    |
| Hypophosphataemia<br>subjects affected / exposed<br>occurrences (all)           | 5 / 59 (8.47%)<br>6    | 1 / 4 (25.00%)<br>1 | 1 / 30 (3.33%)<br>1    |
| Increased appetite                                                              |                        |                     |                        |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 59 (0.00%) | 1 / 4 (25.00%) | 0 / 30 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Hypoglycaemia               |                |                |                |
| subjects affected / exposed | 1 / 59 (1.69%) | 0 / 4 (0.00%)  | 1 / 30 (3.33%) |
| occurrences (all)           | 1              | 0              | 2              |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment                                                                                                         |
|------------------|-------------------------------------------------------------------------------------------------------------------|
| 31 July 2015     | Added exclusion criteria for troponin. Added additional guidance on the collection of triplicate ECGs.            |
| 02 February 2016 | Added details for flat dosing, Added IHC scoring details for Part 2 of the study. Clarified eligibility criteria. |
| 12 April 2016    | Updated eligibility criteria                                                                                      |
| 21 July 2016     | Removed flat dosing option. Added BMS-986148 and Nivolumab combination therapy arm (Part 3).                      |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported