



Clinical trial results:

A Phase 1/2, Open-Label, Dose-Escalation/Dose-Expansion, Safety and Tolerability Study of INCB059872 in Subjects With Advanced Malignancies

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2017-001710-28 |
| Trial protocol | BE |
| Global end of trial date | 14 April 2022 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v2 (current) |
| This version publication date | 01 July 2023 |
| First version publication date | 26 April 2023 |
| Version creation reason | |

Trial information

Trial identification

| | |
|-----------------------|----------------|
| Sponsor protocol code | INCB 59872-101 |
|-----------------------|----------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Incyte Corporation |
| Sponsor organisation address | 1801 Augustine Cutoff Drive, Wilmington, United States, 19803 |
| Public contact | Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.com |
| Scientific contact | Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.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 | 14 April 2022 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 14 April 2022 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

Part 1: To evaluate the safety and tolerability and determine the recommended dose(s) of INCB059872 for further study in advanced malignancies.

Part 2: To further evaluate the safety and tolerability of INCB059872 for further study in advanced malignancies.

Part 3: To evaluate the safety and tolerability and determine the recommended dose of INCB059872 in combination with other therapies for further study in advanced malignancies.

Part 4: To further evaluate the safety and tolerability of INCB059872 in combination with other therapies in advanced malignancies.

Protection of trial subjects:

This study was to have been performed in accordance with ethical principles that have their origin in the Declaration of Helsinki and conducted in adherence to the study Protocol, Good Clinical Practices as defined in Title 21 of the United States Code of Federal Regulations Parts 11, 50, 54, 56, and 312, as well as International Council for Harmonization Good Clinical Practice consolidated guidelines (E6) and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------|
| Actual start date of recruitment | 05 May 2016 |
| 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 | United States: 104 |
| Country: Number of subjects enrolled | Belgium: 9 |
| Country: Number of subjects enrolled | Netherlands: 2 |
| Worldwide total number of subjects | 115 |
| EEA total number of subjects | 11 |

Notes:

Subjects enrolled per age group

| | |
|--|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 | 0 |

| | |
|--|----|
| wk | |
| 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) | 62 |
| From 65 to 84 years | 53 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were enrolled at 12 study sites: 10 in the United States and 1 each in Belgium and the Netherlands.

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 |
| Arm title | Group A: INCB059872 Monotherapy; 2 mg QOD |

Arm description:

Participants with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) received oral INB059872 2 milligrams (mg) as monotherapy once every other day (QOD) on a 28-day continuous therapy cycle.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

1 mg concentration

| | |
|------------------|--|
| Arm title | Group A: INCB059872 Monotherapy; 2 mg QD |
|------------------|--|

Arm description:

Participants with AML or MDS received oral INB059872 2 mg as monotherapy once daily (QD) on a 28-day continuous therapy cycle.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

1 mg concentration

| | |
|------------------|---|
| Arm title | Group A: INCB059872 Monotherapy; 3 mg QOD |
|------------------|---|

Arm description:

Participants with AML or MDS received oral INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|--|
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 1 mg concentration | |
| Arm title | Group A: INCB059872 Monotherapy; 3 mg QD |
| Arm description: | |
| Participants with AML or MDS received oral INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Arm type | Experimental |
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 1 mg concentration | |
| Arm title | Group A: INCB059872 Monotherapy; 4 mg QD |
| Arm description: | |
| Participants with AML or MDS received oral INB059872 4 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Arm type | Experimental |
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 1 mg concentration | |
| Arm title | Group A: INCB059872 Monotherapy; 5 mg QD |
| Arm description: | |
| Participants with AML or MDS received oral INB059872 5 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Arm type | Experimental |
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 1 mg concentration | |
| Arm title | Group B: INCB059872 Monotherapy; 1 mg QD |
| Arm description: | |
| Participants with small cell lung cancer (SCLC) and other solid malignancies (e.g., endocrine tumors) received oral INB059872 1 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Arm type | Experimental |

| | |
|--|---|
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 1 mg concentration | |
| Arm title | Group B: INCB059872 Monotherapy; 2 mg QOD |
| Arm description: | |
| Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 2 mg as monotherapy QOD on a 28-day continuous therapy cycle. | |
| Arm type | Experimental |
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 1 mg concentration | |
| Arm title | Group B: INCB059872 Monotherapy; 2 mg QD |
| Arm description: | |
| Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 2 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Arm type | Experimental |
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 1 mg concentration | |
| Arm title | Group B: INCB059872 Monotherapy; 3 mg QOD |
| Arm description: | |
| Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle. | |
| Arm type | Experimental |
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 1 mg concentration | |
| Arm title | Group B: INCB059872 Monotherapy; 3 mg QD |
| Arm description: | |
| Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Arm type | Experimental |

| | |
|--|---|
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 1 mg concentration | |
| Arm title | Group B: INCB059872 Monotherapy; 4 mg QOD |
| Arm description: | |
| Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 4 mg as monotherapy QOD on a 28-day continuous therapy cycle. | |
| Arm type | Experimental |
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 1 mg concentration | |
| Arm title | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA |
| Arm description: | |
| Participants with relapsed/refractory AML received oral INCB059872 2 mg QD in combination with all-trans retinoic acid (ATRA) (at a starting dose of 45 mg/meters squared [m ²] per day at 2 evenly divided doses) on a 28-day continuous therapy cycle. | |
| Arm type | Experimental |
| Investigational medicinal product name | ATRA |
| Investigational medicinal product code | |
| Other name | tretinoin |
| Pharmaceutical forms | Capsule, soft |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 10 mg concentration | |
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 1 mg concentration | |
| Arm title | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA |
| Arm description: | |
| Participants with relapsed/refractory AML received oral INCB059872 3 mg QD in combination with ATRA (at a starting dose of 45 mg/m ² per day at 2 evenly divided doses) on a 28-day continuous therapy cycle. | |
| Arm type | Experimental |
| Investigational medicinal product name | ATRA |
| Investigational medicinal product code | |
| Other name | tretinoin |
| Pharmaceutical forms | Capsule, soft |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 10 mg concentration | |

| | |
|--|------------|
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

1 mg concentration

| | |
|------------------|---|
| Arm title | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA |
|------------------|---|

Arm description:

Participants with relapsed/refractory AML received oral INCB059872 4 mg QD in combination with ATRA (at a starting dose of 45 mg/m² per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

| | |
|--|---------------|
| Arm type | Experimental |
| Investigational medicinal product name | ATRA |
| Investigational medicinal product code | |
| Other name | tretinoin |
| Pharmaceutical forms | Capsule, soft |
| Routes of administration | Oral use |

Dosage and administration details:

10 mg concentration

| | |
|--|------------|
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

1 mg concentration

| | |
|------------------|--|
| Arm title | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
|------------------|--|

Arm description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 2 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/m² subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

| | |
|--|-------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Azacitidine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for suspension for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

25 mg/milliliter (mL) concentration

| | |
|--|------------|
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

1 mg concentration

| | |
|------------------|--|
| Arm title | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine |
|------------------|--|

Arm description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 3 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75

mg/m² subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

| | |
|--|-------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Azacididine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for suspension for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

25 mg/milliliter (mL) concentration

| | |
|--|------------|
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

1 mg concentration

| | |
|------------------|---|
| Arm title | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab |
|------------------|---|

Arm description:

Participants with SCLC received oral INCB059872 3 mg QOD on a 28-day continuous therapy cycle in combination with nivolumab, administered at 3 mg/kilogram (kg) intravenously over 60 minutes every 2 weeks of each 28-day treatment cycle.

| | |
|--|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | nivolumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

10 mg/mL concentration

| | |
|--|------------|
| Investigational medicinal product name | INCB059872 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

1 mg concentration

| Number of subjects in period 1 | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 3 mg QOD |
|---------------------------------------|--|---|--|
| Started | 3 | 6 | 1 |
| Completed | 0 | 0 | 0 |
| Not completed | 3 | 6 | 1 |
| Adverse event, serious fatal | 2 | 5 | - |
| Physician decision | 1 | - | - |
| Consent withdrawn by subject | - | - | 1 |

| | | | |
|--|---|---|---|
| Unknown; No EOS Form Prior to Site Closure | - | - | - |
| Adverse event, non-fatal | - | - | - |
| Study Terminated by Sponsor | - | - | - |
| Started New Cancer Drug | - | - | - |
| Lost to follow-up | - | 1 | - |

| Number of subjects in period 1 | Group A: INCB059872 Monotherapy; 3 mg QD | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD |
|--|---|---|---|
| Started | 5 | 18 | 2 |
| Completed | 0 | 0 | 0 |
| Not completed | 5 | 18 | 2 |
| Adverse event, serious fatal | 3 | 15 | 1 |
| Physician decision | 1 | - | - |
| Consent withdrawn by subject | - | 2 | - |
| Unknown; No EOS Form Prior to Site Closure | - | - | - |
| Adverse event, non-fatal | - | - | - |
| Study Terminated by Sponsor | - | 1 | - |
| Started New Cancer Drug | - | - | 1 |
| Lost to follow-up | 1 | - | - |

| Number of subjects in period 1 | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QOD | Group B: INCB059872 Monotherapy; 2 mg QD |
|--|---|--|---|
| Started | 3 | 3 | 1 |
| Completed | 0 | 0 | 0 |
| Not completed | 3 | 3 | 1 |
| Adverse event, serious fatal | 3 | 3 | - |
| Physician decision | - | - | - |
| Consent withdrawn by subject | - | - | - |
| Unknown; No EOS Form Prior to Site Closure | - | - | - |
| Adverse event, non-fatal | - | - | 1 |
| Study Terminated by Sponsor | - | - | - |
| Started New Cancer Drug | - | - | - |
| Lost to follow-up | - | - | - |

| Number of subjects in period 1 | Group B: INCB059872 Monotherapy; 3 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 4 mg QOD |
|---------------------------------------|--|---|--|
| Started | 36 | 3 | 7 |
| Completed | 0 | 0 | 0 |
| Not completed | 36 | 3 | 7 |
| Adverse event, serious fatal | 27 | 2 | 5 |

| | | | |
|--|---|---|---|
| Physician decision | 1 | - | - |
| Consent withdrawn by subject | 4 | 1 | 2 |
| Unknown; No EOS Form Prior to Site Closure | - | - | - |
| Adverse event, non-fatal | - | - | - |
| Study Terminated by Sponsor | 2 | - | - |
| Started New Cancer Drug | - | - | - |
| Lost to follow-up | 2 | - | - |

| Number of subjects in period 1 | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA |
|--|---|---|---|
| Started | 5 | 7 | 1 |
| Completed | 0 | 0 | 0 |
| Not completed | 5 | 7 | 1 |
| Adverse event, serious fatal | 5 | 6 | 1 |
| Physician decision | - | - | - |
| Consent withdrawn by subject | - | - | - |
| Unknown; No EOS Form Prior to Site Closure | - | - | - |
| Adverse event, non-fatal | - | - | - |
| Study Terminated by Sponsor | - | 1 | - |
| Started New Cancer Drug | - | - | - |
| Lost to follow-up | - | - | - |

| Number of subjects in period 1 | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab |
|--|--|--|---|
| Started | 7 | 1 | 6 |
| Completed | 0 | 0 | 0 |
| Not completed | 7 | 1 | 6 |
| Adverse event, serious fatal | 3 | 1 | 3 |
| Physician decision | - | - | - |
| Consent withdrawn by subject | 1 | - | 2 |
| Unknown; No EOS Form Prior to Site Closure | 1 | - | - |
| Adverse event, non-fatal | - | - | - |
| Study Terminated by Sponsor | 2 | - | 1 |
| Started New Cancer Drug | - | - | - |
| Lost to follow-up | - | - | - |

Baseline characteristics

Reporting groups

| | |
|--|---|
| Reporting group title | Group A: INCB059872 Monotherapy; 2 mg QOD |
| Reporting group description: Participants with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) received oral INB059872 2 milligrams (mg) as monotherapy once every other day (QOD) on a 28-day continuous therapy cycle. | |
| Reporting group title | Group A: INCB059872 Monotherapy; 2 mg QD |
| Reporting group description: Participants with AML or MDS received oral INB059872 2 mg as monotherapy once daily (QD) on a 28-day continuous therapy cycle. | |
| Reporting group title | Group A: INCB059872 Monotherapy; 3 mg QOD |
| Reporting group description: Participants with AML or MDS received oral INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group A: INCB059872 Monotherapy; 3 mg QD |
| Reporting group description: Participants with AML or MDS received oral INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group A: INCB059872 Monotherapy; 4 mg QD |
| Reporting group description: Participants with AML or MDS received oral INB059872 4 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group A: INCB059872 Monotherapy; 5 mg QD |
| Reporting group description: Participants with AML or MDS received oral INB059872 5 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group B: INCB059872 Monotherapy; 1 mg QD |
| Reporting group description: Participants with small cell lung cancer (SCLC) and other solid malignancies (e.g., endocrine tumors) received oral INB059872 1 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group B: INCB059872 Monotherapy; 2 mg QOD |
| Reporting group description: Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 2 mg as monotherapy QOD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group B: INCB059872 Monotherapy; 2 mg QD |
| Reporting group description: Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 2 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group B: INCB059872 Monotherapy; 3 mg QOD |
| Reporting group description: Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group B: INCB059872 Monotherapy; 3 mg QD |
| Reporting group description: Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group B: INCB059872 Monotherapy; 4 mg QOD |
| Reporting group description: Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 4 mg as monotherapy QOD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA |
| Reporting group description: Participants with relapsed/refractory AML received oral INCB059872 2 mg QD in combination with all- | |

trans retinoic acid (ATRA) (at a starting dose of 45 mg/meters squared [m²] per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

| | |
|-----------------------|---|
| Reporting group title | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA |
|-----------------------|---|

Reporting group description:

Participants with relapsed/refractory AML received oral INCB059872 3 mg QD in combination with ATRA (at a starting dose of 45 mg/m² per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

| | |
|-----------------------|---|
| Reporting group title | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA |
|-----------------------|---|

Reporting group description:

Participants with relapsed/refractory AML received oral INCB059872 4 mg QD in combination with ATRA (at a starting dose of 45 mg/m² per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

| | |
|-----------------------|--|
| Reporting group title | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
|-----------------------|--|

Reporting group description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 2 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/m² subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

| | |
|-----------------------|--|
| Reporting group title | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine |
|-----------------------|--|

Reporting group description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 3 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/m² subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

| | |
|-----------------------|---|
| Reporting group title | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab |
|-----------------------|---|

Reporting group description:

Participants with SCLC received oral INCB059872 3 mg QOD on a 28-day continuous therapy cycle in combination with nivolumab, administered at 3 mg/kilogram (kg) intravenously over 60 minutes every 2 weeks of each 28-day treatment cycle.

| Reporting group values | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 3 mg QOD |
|--|--|---|--|
| Number of subjects | 3 | 6 | 1 |
| Age categorical Units: Subjects | | | |
| Adults (18-64 years) | 2 | 5 | 0 |
| From 65-84 years | 1 | 1 | 1 |
| Age Continuous | | | |
| 120=Unable to report age for a single participant due to privacy concerns. | | | |
| Units: years | | | |
| arithmetic mean | 65.0 | 58.0 | 120 |
| standard deviation | ± 5.20 | ± 9.53 | ± 120 |
| Sex: Female, Male Units: participants | | | |
| Female | 3 | 3 | 0 |
| Male | 0 | 3 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 1 |
| Race/Ethnicity, Customized Units: Subjects | | | |
| White | 3 | 4 | 0 |

| | | | |
|--|---|---|---|
| Black or African American | 0 | 2 | 0 |
| Asian | 0 | 0 | 0 |
| American-Indian/Alaska Native | 0 | 0 | 0 |
| Non-White | 0 | 0 | 0 |
| Unknown/Not Specified | 0 | 0 | 0 |
| Declined to Report | 0 | 0 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 1 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 1 | 0 |
| Not Hispanic or Latino | 3 | 5 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 1 |

| Reporting group values | Group A: INCB059872 Monotherapy; 3 mg QD | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD |
|--|---|---|---|
| Number of subjects | 5 | 18 | 2 |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 2 | 8 | 2 |
| From 65-84 years | 3 | 10 | 0 |
| Age Continuous | | | |
| 120=Unable to report age for a single participant due to privacy concerns. | | | |
| Units: years | | | |
| arithmetic mean | 57.4 | 63.8 | 51.0 |
| standard deviation | ± 21.93 | ± 12.02 | ± 18.38 |
| Sex: Female, Male | | | |
| Units: participants | | | |
| Female | 3 | 9 | 2 |
| Male | 2 | 9 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 0 |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| White | 4 | 15 | 2 |
| Black or African American | 0 | 1 | 0 |
| Asian | 0 | 0 | 0 |
| American-Indian/Alaska Native | 0 | 1 | 0 |
| Non-White | 1 | 0 | 0 |
| Unknown/Not Specified | 0 | 1 | 0 |
| Declined to Report | 0 | 0 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 0 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 2 | 1 |
| Not Hispanic or Latino | 5 | 16 | 1 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 0 |

| Reporting group values | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QOD | Group B: INCB059872 Monotherapy; 2 mg QD |
|--|---|--|---|
| Number of subjects | 3 | 3 | 1 |
| Age categorical Units: Subjects | | | |
| Adults (18-64 years) | 2 | 1 | 1 |
| From 65-84 years | 1 | 2 | 0 |
| Age Continuous | | | |
| 120=Unable to report age for a single participant due to privacy concerns. | | | |
| Units: years | | | |
| arithmetic mean | 46.3 | 63.0 | 120 |
| standard deviation | ± 22.59 | ± 17.09 | ± 120 |
| Sex: Female, Male Units: participants | | | |
| Female | 1 | 3 | 0 |
| Male | 2 | 0 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 1 |
| Race/Ethnicity, Customized Units: Subjects | | | |
| White | 2 | 2 | 0 |
| Black or African American | 0 | 1 | 0 |
| Asian | 1 | 0 | 0 |
| American-Indian/Alaska Native | 0 | 0 | 0 |
| Non-White | 0 | 0 | 0 |
| Unknown/Not Specified | 0 | 0 | 0 |
| Declined to Report | 0 | 0 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 1 |
| Ethnicity (NIH/OMB) Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 3 | 3 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 1 |

| Reporting group values | Group B: INCB059872 Monotherapy; 3 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 4 mg QOD |
|--|--|---|--|
| Number of subjects | 36 | 3 | 7 |
| Age categorical Units: Subjects | | | |
| Adults (18-64 years) | 22 | 3 | 5 |
| From 65-84 years | 14 | 0 | 2 |
| Age Continuous | | | |
| 120=Unable to report age for a single participant due to privacy concerns. | | | |
| Units: years | | | |
| arithmetic mean | 57.8 | 51.0 | 63.0 |
| standard deviation | ± 13.95 | ± 11.53 | ± 4.86 |

| | | | |
|---|----|---|---|
| Sex: Female, Male Units: participants | | | |
| Female | 16 | 0 | 4 |
| Male | 20 | 3 | 3 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 0 |
| Race/Ethnicity, Customized Units: Subjects | | | |
| White | 31 | 3 | 6 |
| Black or African American | 3 | 0 | 1 |
| Asian | 1 | 0 | 0 |
| American-Indian/Alaska Native | 0 | 0 | 0 |
| Non-White | 0 | 0 | 0 |
| Unknown/Not Specified | 1 | 0 | 0 |
| Declined to Report | 0 | 0 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 0 |
| Ethnicity (NIH/OMB) Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 36 | 3 | 7 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 0 |

| Reporting group values | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA |
|--|---|---|---|
| Number of subjects | 5 | 7 | 1 |
| Age categorical Units: Subjects | | | |
| Adults (18-64 years) | 3 | 3 | 1 |
| From 65-84 years | 2 | 4 | 0 |
| Age Continuous | | | |
| 120=Unable to report age for a single participant due to privacy concerns. | | | |
| Units: years | | | |
| arithmetic mean | 61.0 | 63.6 | 120 |
| standard deviation | ± 9.19 | ± 13.83 | ± 120 |
| Sex: Female, Male Units: participants | | | |
| Female | 0 | 4 | 0 |
| Male | 5 | 3 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 1 |
| Race/Ethnicity, Customized Units: Subjects | | | |
| White | 5 | 6 | 0 |
| Black or African American | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 |
| American-Indian/Alaska Native | 0 | 0 | 0 |
| Non-White | 0 | 0 | 0 |
| Unknown/Not Specified | 0 | 0 | 0 |

| | | | |
|--|---|---|---|
| Declined to Report | 0 | 1 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 1 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 5 | 7 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 0 | 1 |

| Reporting group values | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab |
|--|--|--|---|
| Number of subjects | 7 | 1 | 6 |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 1 | 0 | 1 |
| From 65-84 years | 6 | 1 | 5 |
| Age Continuous | | | |
| 120=Unable to report age for a single participant due to privacy concerns. | | | |
| Units: years | | | |
| arithmetic mean | 73.4 | 120 | 68.7 |
| standard deviation | ± 9.02 | ± 120 | ± 9.48 |
| Sex: Female, Male | | | |
| Units: participants | | | |
| Female | 3 | 0 | 3 |
| Male | 4 | 0 | 3 |
| Not Being Reported Due to Privacy Concerns | 0 | 1 | 0 |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| White | 7 | 0 | 6 |
| Black or African American | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 |
| American-Indian/Alaska Native | 0 | 0 | 0 |
| Non-White | 0 | 0 | 0 |
| Unknown/Not Specified | 0 | 0 | 0 |
| Declined to Report | 0 | 0 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 1 | 0 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 7 | 0 | 6 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Not Being Reported Due to Privacy Concerns | 0 | 1 | 0 |

| Reporting group values | Total | | |
|------------------------|-------|--|--|
| Number of subjects | 115 | | |

| | | | |
|--|-----|--|--|
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 62 | | |
| From 65-84 years | 53 | | |
| Age Continuous | | | |
| 120=Unable to report age for a single participant due to privacy concerns. | | | |
| Units: years | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| Sex: Female, Male | | | |
| Units: participants | | | |
| Female | 54 | | |
| Male | 57 | | |
| Not Being Reported Due to Privacy Concerns | 4 | | |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| White | 96 | | |
| Black or African American | 8 | | |
| Asian | 2 | | |
| American-Indian/Alaska Native | 1 | | |
| Non-White | 1 | | |
| Unknown/Not Specified | 2 | | |
| Declined to Report | 1 | | |
| Not Being Reported Due to Privacy Concerns | 4 | | |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 4 | | |
| Not Hispanic or Latino | 107 | | |
| Unknown or Not Reported | 0 | | |
| Not Being Reported Due to Privacy Concerns | 4 | | |

End points

End points reporting groups

| | |
|--|---|
| Reporting group title | Group A: INCB059872 Monotherapy; 2 mg QOD |
| Reporting group description: Participants with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) received oral INB059872 2 milligrams (mg) as monotherapy once every other day (QOD) on a 28-day continuous therapy cycle. | |
| Reporting group title | Group A: INCB059872 Monotherapy; 2 mg QD |
| Reporting group description: Participants with AML or MDS received oral INB059872 2 mg as monotherapy once daily (QD) on a 28-day continuous therapy cycle. | |
| Reporting group title | Group A: INCB059872 Monotherapy; 3 mg QOD |
| Reporting group description: Participants with AML or MDS received oral INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group A: INCB059872 Monotherapy; 3 mg QD |
| Reporting group description: Participants with AML or MDS received oral INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group A: INCB059872 Monotherapy; 4 mg QD |
| Reporting group description: Participants with AML or MDS received oral INB059872 4 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group A: INCB059872 Monotherapy; 5 mg QD |
| Reporting group description: Participants with AML or MDS received oral INB059872 5 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group B: INCB059872 Monotherapy; 1 mg QD |
| Reporting group description: Participants with small cell lung cancer (SCLC) and other solid malignancies (e.g., endocrine tumors) received oral INB059872 1 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group B: INCB059872 Monotherapy; 2 mg QOD |
| Reporting group description: Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 2 mg as monotherapy QOD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group B: INCB059872 Monotherapy; 2 mg QD |
| Reporting group description: Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 2 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group B: INCB059872 Monotherapy; 3 mg QOD |
| Reporting group description: Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group B: INCB059872 Monotherapy; 3 mg QD |
| Reporting group description: Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group B: INCB059872 Monotherapy; 4 mg QOD |
| Reporting group description: Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 4 mg as monotherapy QOD on a 28-day continuous therapy cycle. | |
| Reporting group title | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA |
| Reporting group description: Participants with relapsed/refractory AML received oral INCB059872 2 mg QD in combination with all- | |

trans retinoic acid (ATRA) (at a starting dose of 45 mg/m² per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

| | |
|-----------------------|---|
| Reporting group title | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA |
|-----------------------|---|

Reporting group description:

Participants with relapsed/refractory AML received oral INCB059872 3 mg QD in combination with ATRA (at a starting dose of 45 mg/m² per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

| | |
|-----------------------|---|
| Reporting group title | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA |
|-----------------------|---|

Reporting group description:

Participants with relapsed/refractory AML received oral INCB059872 4 mg QD in combination with ATRA (at a starting dose of 45 mg/m² per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

| | |
|-----------------------|--|
| Reporting group title | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
|-----------------------|--|

Reporting group description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 2 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/m² subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

| | |
|-----------------------|--|
| Reporting group title | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine |
|-----------------------|--|

Reporting group description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 3 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/m² subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

| | |
|-----------------------|---|
| Reporting group title | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab |
|-----------------------|---|

Reporting group description:

Participants with SCLC received oral INCB059872 3 mg QOD on a 28-day continuous therapy cycle in combination with nivolumab, administered at 3 mg/kilogram (kg) intravenously over 60 minutes every 2 weeks of each 28-day treatment cycle.

Primary: Number of participants receiving INCB059872 monotherapy with any treatment-emergent adverse event (TEAE)

| | |
|-----------------|--|
| End point title | Number of participants receiving INCB059872 monotherapy with any treatment-emergent adverse event (TEAE) ^{[1][2]} |
|-----------------|--|

End point description:

Adverse events (AEs) were defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related, that occurred after a participant provided informed consent. Abnormal laboratory values or test results occurring after informed consent constituted AEs only if they induced clinical signs or symptoms, were considered clinically meaningful, required therapy (e.g., hematologic abnormality that required transfusion), or required changes in the study drug(s). TEAEs were defined as AEs either reported for the first time or the worsening of pre-existing events after the first dose of study drug and within 30 days of the last administration of study drug.

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

End point timeframe:

up to 588 days

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: Statistical analysis was not performed 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: Statistical analysis was not performed for this endpoint.

| End point values | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 3 mg QOD | Group A: INCB059872 Monotherapy; 3 mg QD |
|-----------------------------|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 6 | 1 | 5 |
| Units: participants | 3 | 6 | 1 | 5 |

| End point values | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QOD |
|-----------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 18 | 2 | 3 | 3 |
| Units: participants | 18 | 2 | 3 | 3 |

| End point values | Group B: INCB059872 Monotherapy; 2 mg QD | Group B: INCB059872 Monotherapy; 3 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 4 mg QOD |
|-----------------------------|---|--|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 36 | 3 | 7 |
| Units: participants | 1 | 36 | 3 | 7 |

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants receiving INCB059872 combination therapy with any TEAE

| | |
|-----------------|---|
| End point title | Number of participants receiving INCB059872 combination therapy with any TEAE ^[3] ^[4] |
|-----------------|---|

End point description:

AEs were defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related, that occurred after a participant provided informed consent. Abnormal laboratory values or test results occurring after informed consent constituted AEs only if they induced clinical signs or symptoms, were considered clinically meaningful, required therapy (e.g., hematologic abnormality that required transfusion), or required changes in the study drug(s). TEAEs were defined as AEs either reported for the first time or the worsening of pre-existing events after the first dose of study drug and within 30 days of the last administration of study drug.

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

End point timeframe:

up to 1387 days

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: Statistical analysis was not performed 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: Statistical analysis was not performed for this endpoint.

| | | | | |
|-----------------------------|---|---|---|---|
| End point values | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 7 | 1 | 7 |
| Units: participants | 5 | 7 | 1 | 7 |

| | | | | |
|-----------------------------|---|--|--|--|
| End point values | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1 | 6 | | |
| Units: participants | 1 | 6 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Objective response rate (ORR) in participants with the indicated type of solid tumors who received INCB059872 monotherapy

| | |
|-----------------|--|
| End point title | Objective response rate (ORR) in participants with the indicated type of solid tumors who received INCB059872 monotherapy ^[5] |
|-----------------|--|

End point description:

ORR was defined as the percentage of participants who achieved a best overall response of complete response (CR) or a partial response (PR), per investigator assessment according to Response Evaluation Criteria in Solid Tumors version 1.1 (RESIST v1.1), recorded before and including the first event of progressive disease (PD). CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 millimeters (mm). PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. 9999=participants in treatment group did not have indicated type of solid tumor and thus did not contribute to the analysis. PDNTs=poorly differentiated neuroendocrine tumors.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| up to 518 days | |

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: Statistical analysis was not performed for this endpoint.

| End point values | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 3 mg QOD | Group A: INCB059872 Monotherapy; 3 mg QD |
|--|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[6] | 0 ^[7] | 0 ^[8] | 0 ^[9] |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| SCLC; Group B, n=0, 0, 0, 18, 1, 3 Ewing's sarcoma; Group B, n=0, 0, 0, 3, 0, 0 PDNTs; Group B, n=1, 0, 0, 12, 0, 0 Other solid tumors; Group B, n=2, 3, 1, 3, 2, 4 | | | | |

Notes:

[6] - Participants did not have solid tumors and thus did not contribute to the analysis.

[7] - Participants did not have solid tumors and thus did not contribute to the analysis.

[8] - Participants did not have solid tumors and thus did not contribute to the analysis.

[9] - Participants did not have solid tumors and thus did not contribute to the analysis.

| End point values | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QOD |
|--|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[10] | 0 ^[11] | 3 ^[12] | 3 ^[13] |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| SCLC; Group B, n=0, 0, 0, 18, 1, 3 Ewing's sarcoma; Group B, n=0, 0, 0, 3, 0, 0 PDNTs; Group B, n=1, 0, 0, 12, 0, 0 Other solid tumors; Group B, n=2, 3, 1, 3, 2, 4 | | | 9999 9999 0.0 0.0 | 9999 9999 9999 0.0 |

Notes:

[10] - Participants did not have solid tumors and thus did not contribute to the analysis.

[11] - Participants did not have solid tumors and thus did not contribute to the analysis.

[12] - Only participants with the indicated type of solid tumor contributed to the analysis.

[13] - Only participants with the indicated type of solid tumor contributed to the analysis.

| End point values | Group B: INCB059872 Monotherapy; 2 mg QD | Group B: INCB059872 Monotherapy; 3 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 4 mg QOD |
|--|---|--|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 ^[14] | 36 ^[15] | 3 ^[16] | 7 ^[17] |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| SCLC; Group B, n=0, 0, 0, 18, 1, 3 Ewing's sarcoma; Group B, n=0, 0, 0, 3, 0, 0 PDNTs; Group B, n=1, 0, 0, 12, 0, 0 Other solid tumors; Group B, n=2, 3, 1, 3, 2, 4 | 9999 9999 9999 0.0 | 0.0 0.0 0.0 0.0 | 0.0 9999 9999 50.0 | 0.0 9999 9999 0.0 |

Notes:

[14] - Only participants with the indicated type of solid tumor contributed to the analysis.

[15] - Only participants with the indicated type of solid tumor contributed to the analysis.

[16] - Only participants with the indicated type of solid tumor contributed to the analysis.

[17] - Only participants with the indicated type of solid tumor contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR for altering the natural history of the disease in participants with acute myeloid leukemia (AML) who received INCB059872 monotherapy

| | |
|-----------------|---|
| End point title | ORR for altering the natural history of the disease in participants with acute myeloid leukemia (AML) who received INCB059872 monotherapy ^[18] |
|-----------------|---|

End point description:

ORR was defined as the percentage of participants who achieved a best overall response of complete remission or complete remission with incomplete hematologic recovery (CRi), per the International Working Group Response Criteria for AML, recorded before and including the first event of progression (treatment failure, relapse, and PD) based on altering the natural history of the disease. Complete remission: absolute neutrophil count (ANC) $\geq 1.0 \times 10^9/\text{Liter (L)}$, platelet count $\geq 100 \times 10^9/\text{L}$, bone marrow with less than 5% blast cells, Auer rods not detectable; no platelet, or whole blood transfusions for 7 days prior to the date of the hematology assessment. CRi: complete remission, but the ANC count may be $< 1.0 \times 10^9/\text{L}$ and/or the platelet count may be $< 100 \times 10^9/\text{L}$.

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

End point timeframe:

up to 85 days

Notes:

[18] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 3 mg QOD | Group A: INCB059872 Monotherapy; 3 mg QD |
|-----------------------------------|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 ^[19] | 5 ^[20] | 0 ^[21] | 4 ^[22] |
| Units: percentage of participants | | | | |
| number (not applicable) | 0.0 | 0.0 | | 0.0 |

Notes:

[19] - Only participants with AML contributed to the analysis.

[20] - Only participants with AML contributed to the analysis.

[21] - This participant was on treatment for less than a week and therefore was not evaluated for efficacy.

[22] - Only participants with AML contributed to the analysis.

| End point values | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QOD |
|-----------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 ^[23] | 2 ^[24] | 0 ^[25] | 0 ^[26] |
| Units: percentage of participants | | | | |
| number (not applicable) | 0.0 | 0.0 | | |

Notes:

[23] - Only participants with AML contributed to the analysis.

[24] - Only participants with AML contributed to the analysis.

[25] - Participants did not have AML and thus did not contribute to the analysis.

[26] - Participants did not have AML and thus did not contribute to the analysis.

| End point values | Group B: INCB059872 Monotherapy; 2 mg QD | Group B: INCB059872 Monotherapy; 3 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 4 mg QOD |
|-----------------------------------|---|--|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[27] | 0 ^[28] | 0 ^[29] | 0 ^[30] |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |

Notes:

[27] - Participants did not have AML and thus did not contribute to the analysis.

[28] - Participants did not have AML and thus did not contribute to the analysis.

[29] - Participants did not have AML and thus did not contribute to the analysis.

[30] - Participants did not have AML and thus did not contribute to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR for altering the natural history of the disease in participants with myelodysplastic syndrome (MDS) who received INCB059872 monotherapy

| | |
|-----------------|---|
| End point title | ORR for altering the natural history of the disease in participants with myelodysplastic syndrome (MDS) who received INCB059872 monotherapy ^[31] |
|-----------------|---|

End point description:

ORR was defined as the percentage of participants who achieved a best overall response of complete remission, partial remission, or bone marrow complete remission, per the International Working Group Response Criteria for MDS, recorded before and including the first event of progression (treatment failure, relapse after CR or PR, disease transformation, and PD) based on altering the natural history of the disease. Complete remission: <5% bone marrow blasts without evidence of dysplasia; peripheral blood counts: hemoglobin ≥ 11 grams per deciliter (g/dL), neutrophils $\geq 1 \times 10^9/L$, platelets $\geq 100 \times 10^9/L$. Partial remission: meeting complete remission criteria, but bone marrow blasts decreased by $\geq 50\%$ from pre-treatment, but still $\geq 5\%$. Bone marrow complete remission: $\leq 5\%$ bone marrow blasts and decrease by $\geq 50\%$ from pre-treatment.

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

End point timeframe:

up to 61 days

Notes:

[31] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 3 mg QOD | Group A: INCB059872 Monotherapy; 3 mg QD |
|-----------------------------------|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[32] | 1 | 0 ^[33] | 1 |
| Units: percentage of participants | | | | |
| number (not applicable) | | 0.0 | | 0.0 |

Notes:

[32] - Participants did not have MDS and thus did not contribute to the analysis.

[33] - This participant was on treatment for less than a week and therefore was not evaluated for efficacy.

| End point values | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QOD |
|-----------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 6 | 0 ^[34] | 0 ^[35] | 0 ^[36] |
| Units: percentage of participants | | | | |
| number (not applicable) | 0.0 | | | |

Notes:

[34] - Participants did not have MDS and thus did not contribute to the analysis.

[35] - Participants did not have MDS and thus did not contribute to the analysis.

[36] - Participants did not have MDS and thus did not contribute to the analysis.

| End point values | Group B: INCB059872 Monotherapy; 2 mg QD | Group B: INCB059872 Monotherapy; 3 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 4 mg QOD |
|-----------------------------------|---|--|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[37] | 0 ^[38] | 0 ^[39] | 0 ^[40] |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |

Notes:

[37] - Participants did not have MDS and thus did not contribute to the analysis.

[38] - Participants did not have MDS and thus did not contribute to the analysis.

[39] - Participants did not have MDS and thus did not contribute to the analysis.

[40] - Participants did not have MDS and thus did not contribute to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in spleen volume reduction (SVR) at Week 12 in participants with myelofibrosis (MF) who received INCB059872 monotherapy

| | |
|-----------------|--|
| End point title | Change from Baseline in spleen volume reduction (SVR) at Week 12 in participants with myelofibrosis (MF) who received INCB059872 monotherapy ^[41] |
|-----------------|--|

End point description:

Change from Baseline was to have been calculated as the post-Baseline value minus the Baseline value. SVR was to have been measured by magnetic resonance imaging (MRI), or by computed tomography (CT) scan in participants who were not candidates for MRI or when MRI was not readily available.

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

End point timeframe:

Baseline; Week 12

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: Statistical analysis was not performed for this endpoint.

| End point values | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 3 mg QOD | Group A: INCB059872 Monotherapy; 3 mg QD |
|--------------------------------------|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[42] | 0 ^[43] | 0 ^[44] | 0 ^[45] |
| Units: centimeters cubed | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[42] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[43] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[44] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[45] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

| End point values | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QOD |
|--------------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[46] | 0 ^[47] | 0 ^[48] | 0 ^[49] |
| Units: centimeters cubed | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[46] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[47] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[48] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[49] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

| End point values | Group B: INCB059872 Monotherapy; 2 mg QD | Group B: INCB059872 Monotherapy; 3 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 4 mg QOD |
|--------------------------------------|---|--|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[50] | 0 ^[51] | 0 ^[52] | 0 ^[53] |
| Units: centimeters cubed | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[50] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[51] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[52] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[53] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of INCB059872 in plasma when received as monotherapy

| | |
|---|---|
| End point title | Cmax of INCB059872 in plasma when received as |
| End point description: | |
| Cmax was defined as the maximum observed plasma concentration of INCB059872. 9999=To protect participant privacy and mitigate the risk of re-identification, mean (SD) cannot be reported for a single participant. | |
| End point type | Secondary |
| End point timeframe: | |
| Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose | |

Notes:

[54] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 3 mg QOD | Group A: INCB059872 Monotherapy; 3 mg QD |
|--------------------------------------|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 2 | 4 | 0 ^[55] | 3 |
| Units: nanomolar (nM) | | | | |
| arithmetic mean (standard deviation) | 33.4 (± 29.2) | 46.0 (± 12.5) | () | 73.1 (± 30.5) |

Notes:

[55] - No participants contributed to the analysis.

| End point values | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QOD |
|--------------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 1 | 3 | 3 |
| Units: nanomolar (nM) | | | | |
| arithmetic mean (standard deviation) | 110 (± 13.7) | 9999 (± 9999) | 25.7 (± 21.8) | 46.0 (± 9.95) |

| End point values | Group B: INCB059872 Monotherapy; 2 mg QD | Group B: INCB059872 Monotherapy; 3 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 4 mg QOD |
|--------------------------------------|---|--|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[56] | 6 | 1 | 3 |
| Units: nanomolar (nM) | | | | |
| arithmetic mean (standard deviation) | () | 70.6 (± 25.6) | 9999 (± 9999) | 98.2 (± 28.5) |

Notes:

[56] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: tmax of INCB059872 in plasma when received as monotherapy

| | |
|--|---|
| End point title | tmax of INCB059872 in plasma when received as |
| End point description: | |
| tmax was defined as the time to the maximum observed plasma concentration of INCB059872. 9999=To protect participant privacy and mitigate the risk of re-identification, median (full range) cannot be reported for a single participant | |
| End point type | Secondary |
| End point timeframe: | |
| Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose | |

Notes:

[57] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 3 mg QOD | Group A: INCB059872 Monotherapy; 3 mg QD |
|-------------------------------|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 2 | 4 | 0 ^[58] | 3 |
| Units: hours | | | | |
| median (full range (min-max)) | 0.5 (0.5 to 0.5) | 1 (0.5 to 1) | (to) | 1 (0.5 to 1) |

Notes:

[58] - No participants contributed to the analysis.

| End point values | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QOD |
|-------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 1 | 3 | 3 |
| Units: hours | | | | |
| median (full range (min-max)) | 0.5 (0.5 to 1) | 9999 (9999 to 9999) | 2.0 (0.5 to 2) | 2 (0.5 to 2) |

| End point values | Group B: INCB059872 Monotherapy; 2 mg QD | Group B: INCB059872 Monotherapy; 3 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 4 mg QOD |
|-------------------------------|---|--|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[59] | 6 | 1 | 3 |
| Units: hours | | | | |
| median (full range (min-max)) | (to) | 1 (0.5 to 2) | 9999 (9999 to 9999) | 0.5 (0.5 to 1) |

Notes:

[59] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-τ) of INCB059872 in plasma when received as monotherapy

| | |
|-----------------|---|
| End point title | AUC(0-τ) of INCB059872 in plasma when received as monotherapy ^[60] |
|-----------------|---|

End point description:

AUC(0-τ) was defined as the area under the plasma concentration-time curve from time = 0 to the end of the dosing period of INCB059872. 9999=To protect participant privacy and mitigate the risk of re-identification, mean (SD) cannot be reported for a single participant.

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

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[60] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 3 mg QOD | Group A: INCB059872 Monotherapy; 3 mg QD |
|--------------------------------------|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 2 | 4 | 0 ^[61] | 3 |
| Units: nM x hour | | | | |
| arithmetic mean (standard deviation) | 196 (± 8.38) | 216 (± 75.5) | () | 374 (± 120) |

Notes:

[61] - No participants contributed to the analysis.

| End point values | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QOD |
|--------------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 1 | 1 | 1 |
| Units: nM x hour | | | | |
| arithmetic mean (standard deviation) | 486 (± 107) | 9999 (± 9999) | 9999 (± 9999) | 9999 (± 9999) |

| End point values | Group B: INCB059872 Monotherapy; 2 mg QD | Group B: INCB059872 Monotherapy; 3 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 4 mg QOD |
|--------------------------------------|---|--|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[62] | 6 | 1 | 3 |
| Units: nM x hour | | | | |
| arithmetic mean (standard deviation) | () | 361 (± 115) | 9999 (± 9999) | 495 (± 63.2) |

Notes:

[62] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: t_{1/2} of INCB059872 in plasma when received as monotherapy

| | |
|-----------------|---|
| End point title | t _{1/2} of INCB059872 in plasma when received as |
|-----------------|---|

End point description:

t_{1/2} was defined as the half-life of INCB059872. 9999=To protect participant privacy and mitigate the risk of re-identification, mean (SD) cannot be reported for a single participant.

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

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[63] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 3 mg QOD | Group A: INCB059872 Monotherapy; 3 mg QD |
|--------------------------------------|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 2 | 4 | 0 ^[64] | 3 |
| Units: hours | | | | |
| arithmetic mean (standard deviation) | 3.15 (± 0.189) | 3.30 (± 0.765) | () | 3.13 (± 0.495) |

Notes:

[64] - No participants contributed to the analysis.

| End point values | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QOD |
|--------------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 1 | 1 | 1 |
| Units: hours | | | | |
| arithmetic mean (standard deviation) | 3.67 (± 1.38) | 9999 (± 9999) | 9999 (± 9999) | 9999 (± 9999) |

| End point values | Group B: INCB059872 Monotherapy; 2 mg QD | Group B: INCB059872 Monotherapy; 3 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 4 mg QOD |
|--------------------------------------|---|--|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[65] | 6 | 1 | 3 |
| Units: hours | | | | |
| arithmetic mean (standard deviation) | () | 3.57 (± 0.52) | 9999 (± 9999) | 4.28 (± 0.25) |

Notes:

[65] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: CL/F of INCB059872 in plasma when received as monotherapy

| | |
|-----------------|---|
| End point title | CL/F of INCB059872 in plasma when received as |
|-----------------|---|

End point description:

CL/F was defined as the apparent oral clearance of INCB059872. 9999=To protect participant privacy and mitigate the risk of re-identification, mean (SD) cannot be reported for a single participant.

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

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[66] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 3 mg QOD | Group A: INCB059872 Monotherapy; 3 mg QD |
|--------------------------------------|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 2 | 4 | 0 ^[67] | 3 |
| Units: Liters per hour | | | | |
| arithmetic mean (standard deviation) | 32.9 (± 7.94) | 26.3 (± 9.31) | () | 22.1 (± 6.56) |

Notes:

[67] - No participants contributed to the analysis.

| End point values | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QOD |
|--------------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 1 | 1 | 1 |
| Units: Liters per hour | | | | |
| arithmetic mean (standard deviation) | 22.1 (± 5.57) | 9999 (± 9999) | 9999 (± 9999) | 9999 (± 9999) |

| End point values | Group B: INCB059872 Monotherapy; 2 mg QD | Group B: INCB059872 Monotherapy; 3 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 4 mg QOD |
|--------------------------------------|---|--|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[68] | 6 | 1 | 3 |
| Units: Liters per hour | | | | |
| arithmetic mean (standard deviation) | () | 23.1 (± 6.32) | 9999 (± 9999) | 21.1 (± 2.74) |

Notes:

[68] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR in participants with SCLC who received combination therapy

| | |
|-----------------|--|
| End point title | ORR in participants with SCLC who received combination therapy ^[69] |
|-----------------|--|

End point description:

ORR was defined as the percentage of participants who achieved a best overall response of CR or a PR, per investigator assessment according to RESIST v1.1, recorded before and including the first event of PD. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions.

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

End point timeframe:

up to 1353 days

Notes:

[69] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
|-----------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[70] | 0 ^[71] | 0 ^[72] | 0 ^[73] |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |

Notes:

[70] - Participants did not have SCLC and thus did not contribute to the analysis.

[71] - Participants did not have SCLC and thus did not contribute to the analysis.

[72] - Participants did not have SCLC and thus did not contribute to the analysis.

[73] - Participants did not have SCLC and thus did not contribute to the analysis.

| End point values | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab | | |
|-----------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[74] | 5 ^[75] | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | 20.0 | | |

Notes:

[74] - Participants did not have SCLC and thus did not contribute to the analysis.

[75] - Only participants with available data contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR for altering the natural history of the disease in participants with AML who received combination therapy

| | |
|-----------------|---|
| End point title | ORR for altering the natural history of the disease in participants with AML who received combination therapy ^[76] |
|-----------------|---|

End point description:

ORR was defined as the percentage of participants who achieved a best overall response of complete remission or CRi, per the International Working Group Response Criteria for AML, recorded before and including the first event of progression (treatment failure, relapse, and PD) based on altering the natural history of the disease. Complete remission: ANC $\geq 1.0 \times 10^9/L$, platelet count $\geq 100 \times 10^9/L$, bone marrow with less than 5% blast cells, Auer rods not detectable; no platelet, or whole blood transfusions for 7 days prior to the date of the hematology assessment. CRi: complete remission, but the ANC count may be $< 1.0 \times 10^9/L$ and/or the platelet count may be $< 100 \times 10^9/L$.

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

End point timeframe:

up to 208 days

Notes:

[76] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
|-----------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 7 | 1 | 6 ^[77] |
| Units: percentage of participants | | | | |
| number (not applicable) | 20.0 | 0.0 | 0.0 | 16.7 |

Notes:

[77] - Only participants with AML contributed to the analysis.

| End point values | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab | | |
|-----------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1 ^[78] | 0 ^[79] | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 0.0 | | | |

Notes:

[78] - Only participants with AML contributed to the analysis.

[79] - Participants did not have AML and thus did not contribute to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR for altering the natural history of the disease in participants with MDS who received combination therapy

| | |
|-----------------|---|
| End point title | ORR for altering the natural history of the disease in participants with MDS who received combination therapy ^[80] |
|-----------------|---|

End point description:

ORR was defined as the percentage of participants who achieved a best overall response of complete remission, partial remission, or bone marrow complete remission, per the International Working Group Response Criteria for MDS, recorded before and including the first event of progression (treatment failure, relapse after CR or PR, disease transformation, and PD) based on altering the natural history of the disease. Complete remission: <5% bone marrow blasts without evidence of dysplasia; peripheral blood counts: hemoglobin ≥ 11 g/dL, neutrophils $\geq 1 \times 10^9$ /L, platelets $\geq 100 \times 10^9$ /L. Partial remission: meeting complete remission criteria, but bone marrow blasts decreased by $\geq 50\%$ from pre-treatment, but still $\geq 5\%$. Bone marrow complete remission: $\leq 5\%$ bone marrow blasts and decrease by $\geq 50\%$ from pre-treatment.

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

End point timeframe:

up to 85 days

Notes:

[80] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
|-----------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[81] | 0 ^[82] | 0 ^[83] | 1 ^[84] |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | 0.0 |

Notes:

[81] - Participants did not have MDS and thus did not contribute to the analysis.

[82] - Participants did not have MDS and thus did not contribute to the analysis.

[83] - Participants did not have MDS and thus did not contribute to the analysis.

[84] - Only participants with MDS contributed to the analysis.

| End point values | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab | | |
|-----------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[85] | 0 ^[86] | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |

Notes:

[85] - Only participants with MDS contributed to the analysis.

[86] - Participants did not have MDS and thus did not contribute to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of INCB059872 in plasma when received as combination therapy

| | |
|--|---|
| End point title | Cmax of INCB059872 in plasma when received as combination therapy ^[87] |
| End point description: Cmax was defined as the maximum observed plasma concentration of INCB059872. | |
| End point type | Secondary |
| End point timeframe: Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose | |

Notes:

[87] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
|--------------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 2 | 0 ^[88] | 3 |
| Units: nM | | | | |
| arithmetic mean (standard deviation) | 44.3 (± 16.4) | 96.4 (± 10.7) | () | 38.2 (± 33.5) |

Notes:

[88] - No participants contributed to the analysis.

| End point values | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[89] | 5 | | |
| Units: nM | | | | |
| arithmetic mean (standard deviation) | () | 78.0 (± 26.3) | | |

Notes:

[89] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: tmax of INCB059872 in plasma when received as combination therapy

| | |
|-----------------|---|
| End point title | tmax of INCB059872 in plasma when received as combination therapy ^[90] |
|-----------------|---|

End point description:

tmax was defined as the time to the maximum observed plasma concentration of INCB059872.

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

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[90] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
|-------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 2 | 0 ^[91] | 3 |
| Units: hours | | | | |
| median (full range (min-max)) | 1.0 (0.5 to 1) | 0.5 (0.5 to 0.5) | (to) | 0.5 (0 to 1) |

Notes:

[91] - No participants contributed to the analysis.

| End point values | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab | | |
|-------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[92] | 5 | | |
| Units: hours | | | | |
| median (full range (min-max)) | (to) | 1.0 (0.5 to 1) | | |

Notes:

[92] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-τ) of INCB059872 in plasma when received as combination therapy

| | |
|-----------------|---|
| End point title | AUC(0-τ) of INCB059872 in plasma when received as combination therapy ^[93] |
|-----------------|---|

End point description:

AUC(0-τ) was defined as the area under the plasma concentration-time curve from time = 0 to the end of the dosing period of INCB059872.

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

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[93] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
|--------------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 2 | 0 ^[94] | 3 |
| Units: nM x hour | | | | |
| arithmetic mean (standard deviation) | 225 (± 85.9) | 377 (± 25.7) | () | 273 (± 24.4) |

Notes:

[94] - No participants contributed to the analysis.

| End point values | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab | | |
|------------------|---|--|--|--|
|------------------|---|--|--|--|

| | | | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[95] | 5 | | |
| Units: nM x hour | | | | |
| arithmetic mean (standard deviation) | () | 357 (± 97.5) | | |

Notes:

[95] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: t1/2 of INCB059872 in plasma when received as combination therapy

| | |
|-----------------|---|
| End point title | t1/2 of INCB059872 in plasma when received as combination therapy ^[96] |
|-----------------|---|

End point description:

t1/2 was defined as the half-life of INCB059872.

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

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[96] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
|--------------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 2 | 0 ^[97] | 3 |
| Units: hours | | | | |
| arithmetic mean (standard deviation) | 3.95 (± 0.499) | 3.41 (± 0.281) | () | 3.08 (± 0.040) |

Notes:

[97] - No participants contributed to the analysis.

| End point values | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[98] | 5 | | |
| Units: hours | | | | |
| arithmetic mean (standard deviation) | () | 3.79 (± 0.852) | | |

Notes:

[98] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: CL/F of INCB059872 in plasma when received as combination therapy

| | |
|-----------------|---|
| End point title | CL/F of INCB059872 in plasma when received as combination therapy ^[99] |
|-----------------|---|

End point description:

CL/F was defined as the apparent oral clearance of INCB059872.

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

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[99] - 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: Statistical analysis was not performed for this endpoint.

| End point values | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
|--------------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 2 | 0 ^[100] | 3 |
| Units: Liters per hour | | | | |
| arithmetic mean (standard deviation) | 25.1 (± 7.21) | 20.7 (± 1.41) | () | 19.0 (± 1.70) |

Notes:

[100] - No participants contributed to the analysis.

| End point values | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[101] | 5 | | |
| Units: Liters per hour | | | | |
| arithmetic mean (standard deviation) | () | 23.5 (± 8.14) | | |

Notes:

[101] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

up to 1387 days

Adverse event reporting additional description:

Treatment-emergent adverse events, defined as adverse events either reported for the first time or the worsening of pre-existing events after the first dose of study drug and within 30 days of the last administration of study drug, have been reported for the Safety Population.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 25.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Group A: INCB059872 Monotherapy; 2 mg QD |
|-----------------------|--|

Reporting group description:

Participants with AML or MDS received INB059872 2 mg as monotherapy once daily (QD) on a 28-day continuous therapy cycle.

| | |
|-----------------------|---|
| Reporting group title | Group A: INCB059872 Monotherapy; 2 mg QOD |
|-----------------------|---|

Reporting group description:

Participants with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) received INB059872 2 milligrams (mg) as monotherapy once every other day (QOD) on a 28-day continuous therapy cycle.

| | |
|-----------------------|---|
| Reporting group title | Group A: INCB059872 Monotherapy; 3 mg QOD |
|-----------------------|---|

Reporting group description:

Participants with AML or MDS received INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle.

| | |
|-----------------------|--|
| Reporting group title | Group A: INCB059872 Monotherapy; 3 mg QD |
|-----------------------|--|

Reporting group description:

Participants with AML or MDS received INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle.

| | |
|-----------------------|--|
| Reporting group title | Group A: INCB059872 Monotherapy; 4 mg QD |
|-----------------------|--|

Reporting group description:

Participants with AML or MDS received INB059872 4 mg as monotherapy QD on a 28-day continuous therapy cycle.

| | |
|-----------------------|--|
| Reporting group title | Group A: INCB059872 Monotherapy; 5 mg QD |
|-----------------------|--|

Reporting group description:

Participants with AML or MDS received INB059872 5 mg as monotherapy QD on a 28-day continuous therapy cycle.

| | |
|-----------------------|---|
| Reporting group title | Group B: INCB059872 Monotherapy; 2 mg QOD |
|-----------------------|---|

Reporting group description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received INB059872 2 mg as monotherapy QOD on a 28-day continuous therapy cycle.

| | |
|-----------------------|--|
| Reporting group title | Group B: INCB059872 Monotherapy; 1 mg QD |
|-----------------------|--|

Reporting group description:

Participants with small cell lung cancer (SCLC) and other solid malignancies (e.g., endocrine tumors) received INB059872 1 mg as monotherapy QD on a 28-day continuous therapy cycle.

| | |
|-----------------------|--|
| Reporting group title | Group B: INCB059872 Monotherapy; 2 mg QD |
|-----------------------|--|

Reporting group description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received INB059872 2 mg as monotherapy QD on a 28-day continuous therapy cycle.

| | |
|-----------------------|---|
| Reporting group title | Group B: INCB059872 Monotherapy; 4 mg QOD |
|-----------------------|---|

Reporting group description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received INB059872 4 mg

as monotherapy QOD on a 28-day continuous therapy cycle.

| | |
|-----------------------|--|
| Reporting group title | Group B: INCB059872 Monotherapy; 3 mg QD |
|-----------------------|--|

Reporting group description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle.

| | |
|-----------------------|---|
| Reporting group title | Group B: INCB059872 Monotherapy; 3 mg QOD |
|-----------------------|---|

Reporting group description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle.

| | |
|-----------------------|---|
| Reporting group title | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA |
|-----------------------|---|

Reporting group description:

Participants with relapsed/refractory AML received INCB059872 2 mg QD in combination with all-trans retinoic acid (ATRA) (at a starting dose of 45 mg/meters squared [m^2] per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

| | |
|-----------------------|---|
| Reporting group title | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA |
|-----------------------|---|

Reporting group description:

Participants with relapsed/refractory AML received oral INCB059872 3 mg QD in combination with ATRA (at a starting dose of 45 mg/ m^2 per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

| | |
|-----------------------|--|
| Reporting group title | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine |
|-----------------------|--|

Reporting group description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 3 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/ m^2 subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

| | |
|-----------------------|--|
| Reporting group title | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine |
|-----------------------|--|

Reporting group description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 2 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/ m^2 subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

| | |
|-----------------------|---|
| Reporting group title | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA |
|-----------------------|---|

Reporting group description:

Participants with relapsed/refractory AML received oral INCB059872 4 mg QD in combination with ATRA (at a starting dose of 45 mg/ m^2 per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

| | |
|-----------------------|---|
| Reporting group title | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab |
|-----------------------|---|

Reporting group description:

Participants with SCLC received oral INCB059872 3 mg QOD on a 28-day continuous therapy cycle in combination with nivolumab, administered at 3 mg/kilogram (kg) intravenously over 60 minutes every 2 weeks of each 28-day treatment cycle.

| Serious adverse events | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 3 mg QOD |
|---|---|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 6 (83.33%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| number of deaths (all causes) | 5 | 2 | 0 |
| number of deaths resulting from adverse events | 4 | 0 | 0 |

| | | | |
|---|---------------|---------------|---------------|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Blast cell crisis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant neoplasm progression | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| General physical health deterioration | | | |

| | | | |
|---|----------------|---------------|---------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumothorax | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 alveolar haemorrhage | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (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 |
| Pulmonary embolism | | | |

| | | | |
|---|----------------|---------------|---------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (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 |
| Psychiatric disorders | | | |
| Confusional state | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 related reaction | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal compression fracture | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subdural haematoma | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 congestive | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Haemorrhage intracranial | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Headache | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myasthenic syndrome | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|---------------|
| Febrile neutropenia | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (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 |
| Leukocytosis | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (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 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (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 | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (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 |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Swollen tongue | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tongue haemorrhage | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Biliary obstruction | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic failure | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acute febrile neutrophilic dermatosis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 retention | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Adrenal haemorrhage | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (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 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myositis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Temporomandibular joint syndrome | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Atypical pneumonia | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (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 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |

| | | | |
|---|----------------|---------------|---------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Perirectal abscess | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 fungal | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Septic shock | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal skin infection | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection bacterial | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypervolaemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Group A: INCB059872 Monotherapy; 3 mg QD | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 5 (60.00%) | 10 / 18 (55.56%) | 2 / 2 (100.00%) |
| number of deaths (all causes) | 4 | 15 | 2 |
| number of deaths resulting from adverse events | 0 | 2 | 1 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Blast cell crisis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (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 |
| Malignant neoplasm progression | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |

| | | | |
|--|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 | | | |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------|----------------|---------------|
| Pneumothorax | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 alveolar haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Psychiatric disorders | | | |
| Confusional state | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 related reaction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal compression fracture | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------|----------------|---------------|
| Subdural haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 congestive | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 | | | |
| Haemorrhage intracranial | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Headache | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myasthenic syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|-----------------|-----------------|
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (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 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 6 / 18 (33.33%) | 2 / 2 (100.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 8 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Leukocytosis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 0 / 2 (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 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 1 / 2 (50.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------|-----------------|----------------|
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 / 5 (0.00%) | 2 / 18 (11.11%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Swollen tongue | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 1 / 2 (50.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tongue haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 1 / 2 (50.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (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 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |

| | | | |
|---|---------------|----------------|---------------|
| Biliary obstruction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acute febrile neutrophilic dermatosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 retention | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Adrenal haemorrhage | | | |

| | | | |
|--|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (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 |
| Myositis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Temporomandibular joint syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 | | | |
| Atypical pneumonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|-----------------|----------------|
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (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 |
| Enterococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 1 / 2 (50.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 1 / 2 (50.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Perirectal abscess | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 | 1 / 5 (20.00%) | 2 / 18 (11.11%) | 1 / 2 (50.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Pneumonia fungal | | | |

| | | | |
|---|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 1 / 2 (50.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal skin infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection bacterial | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 1 / 2 (50.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| 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 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypervolaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (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 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Group B: INCB059872 Monotherapy; 2 mg QOD | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QD |
|--|--|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 2 / 3 (66.67%) | 1 / 1 (100.00%) |
| number of deaths (all causes) | 3 | 3 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Blast cell crisis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant neoplasm progression | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tumour pain | | | |

| | | | |
|--|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (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 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumothorax | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 alveolar haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Confusional state | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|----------------|---------------|---------------|
| Fall | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 related reaction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal compression fracture | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subdural haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 congestive | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |

| | | | |
|---|---------------|----------------|-----------------|
| Haemorrhage intracranial | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Headache | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myasthenic syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (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 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 1 (100.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |

| | | | |
|---|---------------|---------------|---------------|
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Swollen tongue | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tongue haemorrhage | | | |

| | | | |
|---|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Biliary obstruction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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%) | 1 / 3 (33.33%) | 0 / 1 (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 |
| Hepatic failure | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acute febrile neutrophilic dermatosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 retention | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Adrenal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myositis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------|----------------|---------------|
| Temporomandibular joint syndrome subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Atypical pneumonia subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (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 |
| Cellulitis subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterococcal bacteraemia subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia bacteraemia subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Klebsiella bacteraemia subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Perirectal abscess | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 fungal | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal skin infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection bacterial | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Decreased appetite | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypervolaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| 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 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Group B: INCB059872 Monotherapy; 4 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 3 mg QOD |
|---|--|---|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 2 / 3 (66.67%) | 24 / 36 (66.67%) |
| number of deaths (all causes) | 5 | 2 | 27 |
| number of deaths resulting from adverse events | 0 | 0 | 6 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Blast cell crisis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant neoplasm progression | | | |

| | | | |
|--|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| General disorders and administration site conditions | | | |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 36 (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 |

| | | | |
|---|---------------|----------------|----------------|
| Pyrexia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 3 / 36 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumothorax | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary alveolar haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |

| | | | |
|---|---------------|----------------|----------------|
| Psychiatric disorders | | | |
| Confusional state | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 36 (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 |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal compression fracture | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subdural haematoma | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 congestive | | | |

| | | | |
|---|---------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 | | | |
| Haemorrhage intracranial | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Headache | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myasthenic syndrome | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Leukocytosis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 / 7 (0.00%) | 1 / 3 (33.33%) | 3 / 36 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (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 haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal haemorrhage | | | |

| | | | |
|---|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Swollen tongue | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tongue haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (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 | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Biliary obstruction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic failure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|---------------|---------------|----------------|
| Acute febrile neutrophilic dermatosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 retention | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Adrenal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Flank pain | | | |

| | | | |
|---|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myositis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (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 |
| Temporomandibular joint syndrome | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 | | | |
| Atypical pneumonia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (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 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterococcal bacteraemia | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Perirectal abscess | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia fungal | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 36 (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 |
| Septic shock | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal skin infection | | | |

| | | | |
|---|---------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection bacterial | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| 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 | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypervolaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|-------------------------------|----------|----------|----------|
| Serious adverse events | Group C: | Group C: | Group D: |
|-------------------------------|----------|----------|----------|

| | Combination Therapy; INCB059872 2 mg QD + ATRA | Combination Therapy; INCB059872 3 mg QD + ATRA | Combination Therapy; INCB059872 3 mg QD + azacitidine |
|---|---|---|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 4 / 5 (80.00%) | 4 / 7 (57.14%) | 1 / 1 (100.00%) |
| number of deaths (all causes) | 5 | 6 | 1 |
| number of deaths resulting from adverse events | 0 | 2 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Blast cell crisis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant neoplasm progression | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Shock haemorrhagic | | | |

| | | | |
|--|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumothorax | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 alveolar haemorrhage subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders Confusional state subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications Fall subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 related reaction subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal compression fracture subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subdural haematoma subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Haemorrhage intracranial | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Headache | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myasthenic syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 3 / 5 (60.00%) | 2 / 7 (28.57%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 1 / 1 (100.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------|---------------|---------------|
| Nausea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Swollen tongue | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tongue haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Biliary obstruction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acute febrile neutrophilic dermatosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Urinary retention | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Adrenal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (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 |
| Back pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myositis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Temporomandibular joint syndrome | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Infections and infestations | | | |
| Atypical pneumonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |

| | | | |
|---|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (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 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Perirectal abscess | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | 1 / 5 (20.00%) | 1 / 7 (14.29%) | 0 / 1 (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 |
| Pneumonia fungal | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Sepsis | | | |

| | | | |
|---|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal skin infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (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 |
| Urinary tract infection bacterial | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypervolaemia | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab |
|---|--|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 6 / 7 (85.71%) | 0 / 1 (0.00%) | 2 / 6 (33.33%) |
| number of deaths (all causes) | 3 | 1 | 3 |
| number of deaths resulting from adverse events | 0 | 0 | 1 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Blast cell crisis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant neoplasm progression | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| Deep vein thrombosis | | | |

| | | | |
|--|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (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 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------|---------------|----------------|
| Hypoxia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumothorax | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 alveolar haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Confusional state | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 related reaction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|---------------|---------------|
| Spinal compression fracture subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subdural haematoma subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 congestive subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (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 |
| Tricuspid valve incompetence subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (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 |
| Nervous system disorders | | | |
| Haemorrhage intracranial subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Headache subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|---------------|---------------|
| Myasthenic syndrome | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (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 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------|---------------|---------------|
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Swollen tongue | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tongue haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| Biliary obstruction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic failure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acute febrile neutrophilic dermatosis | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 retention | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------|---------------|---------------|
| Endocrine disorders | | | |
| Adrenal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myositis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Temporomandibular joint syndrome | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| Atypical pneumonia | | | |

| | | | |
|---|----------------|---------------|---------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (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 |
| Enterococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Perirectal abscess | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (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 | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 fungal | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal skin infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection bacterial | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to thrive | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypervolaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 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 %

| Non-serious adverse events | Group A: INCB059872 Monotherapy; 2 mg QD | Group A: INCB059872 Monotherapy; 2 mg QOD | Group A: INCB059872 Monotherapy; 3 mg QOD |
|---|---|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 6 / 6 (100.00%) | 3 / 3 (100.00%) | 1 / 1 (100.00%) |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| General disorders and administration site conditions | | | |

| | | | |
|-----------------------------|----------------|-----------------|---------------|
| Asthenia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Face oedema | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 3 (100.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hernia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------|----------------|---------------|
| Oedema | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Breast pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast tenderness | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |

| | | | |
|-----------------------------|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hiccups | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoxia | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Laryngeal haemorrhage | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |

| | | | |
|---|----------------|---------------|---------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Delirium | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood thyroid stimulating hormone | | | |

| | | | |
|--|---------------|---------------|-----------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood triglycerides increased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urea increased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count increased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Prothrombin time prolonged | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Troponin increased | | | |

| | | | |
|--|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Troponin I increased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subcutaneous haematoma | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subdural haematoma | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sunburn | | | |

| | | | |
|------------------------------|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Synovial rupture | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial enlargement | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Burning sensation | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |

| | | | |
|--------------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dysgeusia | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Taste disorder | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Coagulopathy | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haemorrhagic diathesis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|----------------|---------------|---------------|
| Leukopenia | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye irritation | | | |

| | | | |
|-----------------------------|----------------|---------------|---------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye inflammation | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lacrimation increased | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cheilitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

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|----------------------------------|---------------|----------------|---------------|
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival hypertrophy | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

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| Lip dry | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 2 / 3 (66.67%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Oesophageal fistula | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral blood blister | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral disorder | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|--|---------------------|---------------------|--------------------|
| Tongue haematoma subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Vomiting subjects affected / exposed occurrences (all) | 2 / 6 (33.33%) 2 | 1 / 3 (33.33%) 2 | 0 / 1 (0.00%) 0 |
| Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all) | 1 / 6 (16.67%) 1 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Blister subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Blood blister subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Dry skin subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Ecchymosis subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 1 (0.00%) 0 |
| Erythema multiforme subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hyperhidrosis subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Nail disorder subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Palmar erythema | | | |

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|-----------------------------|---------------|----------------|-----------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin ulcer | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin lesion | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin irritation | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitiligo | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |

| | | | |
|---|----------------|----------------|-----------------|
| Dysuria | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nocturia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Adrenal insufficiency | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Chondrocalcinosis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |

| | | | |
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| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infections and infestations | | | |
| Actinomycosis | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Catheter site cellulitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|------------------------------------|----------------|----------------|---------------|
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail infection | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onychomycosis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Osteomyelitis | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular device infection | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Decreased appetite | | | |

| | | | |
|-----------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 2 / 6 (33.33%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypophosphataemia | | | |

| | | | |
|-----------------------------|----------------|---------------|---------------|
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Iron deficiency | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | Group A: INCB059872 Monotherapy; 3 mg QD | Group A: INCB059872 Monotherapy; 4 mg QD | Group A: INCB059872 Monotherapy; 5 mg QD |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 5 / 5 (100.00%) | 17 / 18 (94.44%) | 2 / 2 (100.00%) |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 18 (11.11%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 18 (11.11%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |

| | | | |
|-----------------------------|----------------|-----------------|----------------|
| Face oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 6 / 18 (33.33%) | 1 / 2 (50.00%) |
| occurrences (all) | 2 | 6 | 1 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hernia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 4 / 18 (22.22%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 3 / 18 (16.67%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|----------------|-----------------|---------------|
| Reproductive system and breast disorders | | | |
| Breast pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast tenderness | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cough | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 3 / 18 (16.67%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hiccups | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoxia | | | |

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| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Laryngeal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 18 (11.11%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Delirium | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
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| Insomnia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood thyroid stimulating hormone | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Blood triglycerides increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urea increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| International normalised ratio | | | |

| | | | |
|--|----------------|-----------------|----------------|
| increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 3 / 18 (16.67%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 3 / 18 (16.67%) | 1 / 2 (50.00%) |
| occurrences (all) | 1 | 3 | 1 |
| Platelet count increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prothrombin time prolonged | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Troponin increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Troponin I increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 18 (11.11%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fall | | | |

| | | | |
|-----------------------------|----------------|----------------|---------------|
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subcutaneous haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subdural haematoma | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sunburn | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Synovial rupture | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cardiac disorders | | | |
| Atrial enlargement | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|--|---------------------|----------------------|----------------------|
| Sinus tachycardia subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 2 / 18 (11.11%) 2 | 0 / 2 (0.00%) 0 |
| Tachycardia subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 18 (0.00%) 0 | 2 / 2 (100.00%) 2 |
| Tricuspid valve incompetence subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Nervous system disorders | | | |
| Burning sensation subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Cerebral infarction subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 18 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Dizziness subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 2 / 18 (11.11%) 2 | 0 / 2 (0.00%) 0 |
| Dysgeusia subjects affected / exposed occurrences (all) | 2 / 5 (40.00%) 2 | 3 / 18 (16.67%) 3 | 0 / 2 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 2 / 5 (40.00%) 2 | 2 / 18 (11.11%) 2 | 0 / 2 (0.00%) 0 |
| Neuropathy peripheral subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Paraesthesia subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Somnolence subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Taste disorder | | | |

| | | | |
|--------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 8 / 18 (44.44%) | 1 / 2 (50.00%) |
| occurrences (all) | 2 | 8 | 1 |
| Coagulopathy | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 3 / 18 (16.67%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Haemorrhagic diathesis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 18 (11.11%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 3 / 18 (16.67%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 6 / 18 (33.33%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 9 | 0 |

| | | | |
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| Ear and labyrinth disorders | | | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye inflammation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lacrimation increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal distension | | | |

| | | | |
|----------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cheilitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 18 (11.11%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 2 | 1 |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 3 / 18 (16.67%) | 1 / 2 (50.00%) |
| occurrences (all) | 2 | 3 | 1 |
| Dry mouth | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |

| | | | |
|-----------------------------|----------------|-----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gingival hypertrophy | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nausea | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 7 / 18 (38.89%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 7 | 0 |
| Oesophageal fistula | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral blood blister | | | |

| | | | |
|--|---------------|-----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral disorder | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tongue haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 7 / 18 (38.89%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 7 | 0 |
| Hepatobiliary disorders | | | |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blister | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood blister | | | |

| | | | |
|-----------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Erythema multiforme | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nail disorder | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palmar erythema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 18 (11.11%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Rash macular | | | |

| | | | |
|---|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin ulcer | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin lesion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin irritation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitiligo | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Dysuria | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nocturia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Adrenal insufficiency | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|-----------------------------|----------------|-----------------|----------------|
| Arthralgia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 4 / 18 (22.22%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Chondrocalcinosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 3 / 18 (16.67%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Infections and infestations | | | |
| Actinomycosis | | | |

| | | | |
|-----------------------------|----------------|-----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Catheter site cellulitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 18 (11.11%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onychomycosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Osteomyelitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |

| | | | |
|------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular device infection | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 5 / 18 (27.78%) | 1 / 2 (50.00%) |
| occurrences (all) | 1 | 5 | 1 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 1 / 2 (50.00%) |
| occurrences (all) | 2 | 1 | 1 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|-----------------------------|----------------|-----------------|----------------|
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 1 / 2 (50.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 3 / 18 (16.67%) | 1 / 2 (50.00%) |
| occurrences (all) | 1 | 3 | 1 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 1 / 2 (50.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 18 (5.56%) | 1 / 2 (50.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 1 / 18 (5.56%) | 0 / 2 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Iron deficiency | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 18 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | Group B: INCB059872 Monotherapy; 2 mg QOD | Group B: INCB059872 Monotherapy; 1 mg QD | Group B: INCB059872 Monotherapy; 2 mg QD |
|---|--|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 3 / 3 (100.00%) | 3 / 3 (100.00%) | 1 / 1 (100.00%) |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |

| | | | |
|--|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Face oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 2 / 3 (66.67%) | 0 / 1 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hernia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |

| | | | |
|---|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Reproductive system and breast disorders | | | |
| Breast pain | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Breast tenderness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |

| | | | |
|-----------------------------|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hiccups | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngeal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary oedema | | | |

| | | | |
|---|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Delirium | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | | | |

| | | | |
|--|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood thyroid stimulating hormone | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood triglycerides increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urea increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Platelet count increased | | | |

| | | | |
|--|----------------|---------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prothrombin time prolonged | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Troponin increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Troponin I increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subcutaneous haematoma | | | |

| | | | |
|------------------------------|----------------|---------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subdural haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sunburn | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Synovial rupture | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial enlargement | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Burning sensation | | | |

| | | | |
|--------------------------------------|-----------------|----------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Headache | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Taste disorder | | | |
| subjects affected / exposed | 3 / 3 (100.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Coagulopathy | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|------------------------------|----------------|---------------|-----------------|
| Haemorrhagic diathesis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vertigo | | | |

| | | | |
|--|---------------------|--------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Eye disorders | | | |
| Conjunctival haemorrhage subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Eye irritation subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Eye inflammation subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Lacrimation increased subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Vision blurred subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Vitreous floaters subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort subjects affected / exposed occurrences (all) | 1 / 3 (33.33%) 1 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Abdominal distension subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Abdominal pain subjects affected / exposed occurrences (all) | 1 / 3 (33.33%) 1 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Abdominal pain lower subjects affected / exposed occurrences (all) | 1 / 3 (33.33%) 1 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Abdominal pain upper | | | |

| | | | |
|----------------------------------|-----------------|----------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cheilitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 3 / 3 (100.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival hypertrophy | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival pain | | | |

| | | | |
|-----------------------------|----------------|---------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Oesophageal fistula | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral blood blister | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral disorder | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rectal haemorrhage | | | |

| | | | |
|--|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tongue haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blister | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood blister | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Erythema multiforme | | | |

| | | | |
|-----------------------------|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail disorder | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palmar erythema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin ulcer | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin lesion | | | |

| | | | |
|---|---------------------|---------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Skin irritation subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Vitiligo subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all) | 1 / 3 (33.33%) 1 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Haematuria subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Nocturia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hypothyroidism subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 1 (0.00%) 0 |
| Arthritis subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Back pain subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Chondrocalcinosis | | | |

| | | | |
|-----------------------------|----------------|---------------|---------------|
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Actinomycosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Catheter site cellulitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|---------------|---------------|---------------|
| Fungal infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onychomycosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Osteomyelitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---------------------|--------------------|--------------------|
| Vascular device infection subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration subjects affected / exposed occurrences (all) | 1 / 3 (33.33%) 1 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Decreased appetite subjects affected / exposed occurrences (all) | 1 / 3 (33.33%) 1 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hypercalcaemia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hyperglycaemia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hyperkalaemia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hypertriglyceridaemia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hyperuricaemia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hypoalbuminaemia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hypocalcaemia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hypoglycaemia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hypokalaemia | | | |

| | | | |
|-----------------------------|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Iron deficiency | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | Group B: INCB059872 Monotherapy; 4 mg QOD | Group B: INCB059872 Monotherapy; 3 mg QD | Group B: INCB059872 Monotherapy; 3 mg QOD |
|---|--|---|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 7 (100.00%) | 3 / 3 (100.00%) | 35 / 36 (97.22%) |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 1 | 0 | 1 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 0 | 0 | 2 |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|----------------|----------------|------------------|
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Face oedema | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 4 / 7 (57.14%) | 2 / 3 (66.67%) | 17 / 36 (47.22%) |
| occurrences (all) | 4 | 3 | 19 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Hernia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 3 / 36 (8.33%) |
| occurrences (all) | 0 | 0 | 3 |

| | | | |
|---|----------------|----------------|-----------------|
| Pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 0 | 0 | 2 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 0 | 0 | 2 |
| Reproductive system and breast disorders | | | |
| Breast pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast tenderness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 1 / 3 (33.33%) | 2 / 36 (5.56%) |
| occurrences (all) | 3 | 1 | 2 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 7 / 36 (19.44%) |
| occurrences (all) | 1 | 0 | 7 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epistaxis | | | |

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|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hiccups | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 2 / 36 (5.56%) |
| occurrences (all) | 0 | 1 | 2 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Laryngeal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |

| | | | |
|---|----------------|----------------|-----------------|
| Anxiety | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Delirium | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 3 / 36 (8.33%) |
| occurrences (all) | 0 | 0 | 3 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 5 / 36 (13.89%) |
| occurrences (all) | 0 | 0 | 5 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 0 | 0 | 2 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 3 (33.33%) | 3 / 36 (8.33%) |
| occurrences (all) | 1 | 1 | 4 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 3 / 36 (8.33%) |
| occurrences (all) | 1 | 0 | 3 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 3 / 36 (8.33%) |
| occurrences (all) | 0 | 0 | 4 |
| Blood thyroid stimulating hormone | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood creatinine increased | | | |

| | | | |
|--|----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 1 | 0 | 2 |
| Blood triglycerides increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urea increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 2 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 3 (0.00%) | 3 / 36 (8.33%) |
| occurrences (all) | 3 | 0 | 4 |
| Platelet count decreased | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 1 / 3 (33.33%) | 7 / 36 (19.44%) |
| occurrences (all) | 4 | 1 | 8 |
| Platelet count increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prothrombin time prolonged | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Troponin increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Troponin I increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 3 | 0 | 2 |

| | | | |
|--|---------------------|--------------------|---------------------|
| White blood cell count decreased subjects affected / exposed occurrences (all) | 2 / 7 (28.57%) 2 | 0 / 3 (0.00%) 0 | 2 / 36 (5.56%) 4 |
| Injury, poisoning and procedural complications | | | |
| Contusion subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Fall subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 2 / 36 (5.56%) 2 |
| Post procedural haemorrhage subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Procedural pain subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Skin laceration subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Subcutaneous haematoma subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Subdural haematoma subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Sunburn subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Synovial rupture subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Transfusion reaction subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Cardiac disorders | | | |

| | | | |
|--|---------------------|---------------------|----------------------|
| Atrial enlargement subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Atrial fibrillation subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Pericardial effusion subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Sinus tachycardia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Tachycardia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Tricuspid valve incompetence subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Nervous system disorders | | | |
| Burning sensation subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Cerebral infarction subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Dizziness subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 3 (0.00%) 0 | 2 / 36 (5.56%) 2 |
| Dysgeusia subjects affected / exposed occurrences (all) | 3 / 7 (42.86%) 3 | 2 / 3 (66.67%) 2 | 4 / 36 (11.11%) 4 |
| Headache subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 36 (0.00%) 0 |
| Neuropathy peripheral | | | |

| | | | |
|--------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Taste disorder | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 3 (33.33%) | 3 / 36 (8.33%) |
| occurrences (all) | 1 | 1 | 4 |
| Coagulopathy | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhagic diathesis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 2 / 3 (66.67%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|---------------------|---------------------|----------------------|
| Lymphopenia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 36 (0.00%) 0 |
| Neutropenia subjects affected / exposed occurrences (all) | 2 / 7 (28.57%) 2 | 2 / 3 (66.67%) 2 | 3 / 36 (8.33%) 4 |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 4 / 7 (57.14%) 5 | 2 / 3 (66.67%) 5 | 8 / 36 (22.22%) 9 |
| Ear and labyrinth disorders Deafness neurosensory subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 36 (0.00%) 0 |
| Ear pain subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Hypoacusis subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Vertigo subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Eye disorders Conjunctival haemorrhage subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Eye irritation subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Eye inflammation subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Lacrimation increased subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Vision blurred | | | |

| | | | |
|-----------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 0 | 0 | 2 |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 1 | 0 | 2 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 6 / 36 (16.67%) |
| occurrences (all) | 0 | 0 | 6 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cheilitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 3 (33.33%) | 7 / 36 (19.44%) |
| occurrences (all) | 2 | 2 | 8 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 4 / 36 (11.11%) |
| occurrences (all) | 1 | 0 | 5 |
| Dry mouth | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 1 | 0 | 1 |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|----------------------------------|----------------|----------------|----------------|
| Dysphagia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival hypertrophy | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|----------------|----------------|------------------|
| Nausea | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 3 (0.00%) | 10 / 36 (27.78%) |
| occurrences (all) | 2 | 0 | 10 |
| Oesophageal fistula | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral blood blister | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral disorder | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 3 / 36 (8.33%) |
| occurrences (all) | 1 | 0 | 3 |
| Toothache | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Tongue haematoma | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 3 (33.33%) | 5 / 36 (13.89%) |
| occurrences (all) | 1 | 1 | 5 |
| Hepatobiliary disorders | | | |
| Hyperbilirubinaemia | | | |

| | | | |
|--|--------------------|--------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Blister | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood blister | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Erythema multiforme | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail disorder | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palmar erythema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---------------------|--------------------|---------------------|
| Rash pruritic subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Rash maculo-papular subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Rash macular subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Rash erythematous subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Skin ulcer subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Skin lesion subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Skin irritation subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Vitiligo subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Renal and urinary disorders | | | |
| Dysuria subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Haematuria subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Nocturia | | | |

| | | | |
|--|--------------------|--------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Endocrine disorders | | | |
| Adrenal insufficiency | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypothyroidism | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 1 | 0 | 1 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 5 / 36 (13.89%) |
| occurrences (all) | 0 | 0 | 5 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Back pain | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 3 / 36 (8.33%) |
| occurrences (all) | 1 | 0 | 4 |
| Chondrocalcinosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 1 | 0 | 2 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 1 | 0 | 1 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 3 / 36 (8.33%) |
| occurrences (all) | 0 | 0 | 3 |
| Neck pain | | | |

| | | | |
|-----------------------------|---------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 0 | 0 | 2 |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Actinomycosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Catheter site cellulitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|------------------------------------|----------------|----------------|-----------------|
| Onychomycosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Osteomyelitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 0 | 0 | 2 |
| Vascular device infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 3 (33.33%) | 7 / 36 (19.44%) |
| occurrences (all) | 1 | 1 | 7 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperglycaemia | | | |

| | | | |
|-----------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 3 (33.33%) | 3 / 36 (8.33%) |
| occurrences (all) | 1 | 1 | 3 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 3 / 36 (8.33%) |
| occurrences (all) | 0 | 0 | 3 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 36 (5.56%) |
| occurrences (all) | 0 | 0 | 2 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 3 / 36 (8.33%) |
| occurrences (all) | 0 | 0 | 3 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all) | 0 | 0 | 2 |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 4 / 36 (11.11%) |
| occurrences (all) | 1 | 0 | 4 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 3 / 36 (8.33%) |
| occurrences (all) | 3 | 0 | 3 |
| Iron deficiency | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| Non-serious adverse events | Group C: Combination Therapy; INCB059872 2 mg QD + ATRA | Group C: Combination Therapy; INCB059872 3 mg QD + ATRA | Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine |
|--|--|--|---|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 4 / 5 (80.00%) | 7 / 7 (100.00%) | 1 / 1 (100.00%) |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Face oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |

| | | | |
|--|----------------|----------------|---------------|
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 7 (28.57%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hernia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Breast pain | | | |

| | | | |
|---|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast tenderness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 7 (28.57%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hiccups | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoxia | | | |

| | | | |
|-----------------------------|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngeal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Delirium | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------|---------------|---------------|
| Insomnia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood thyroid stimulating hormone | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood triglycerides increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urea increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio | | | |

| | | | |
|--|----------------|----------------|-----------------|
| increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 7 (14.29%) | 1 / 1 (100.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Platelet count increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prothrombin time prolonged | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Troponin increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Troponin I increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |

| | | | |
|---|--------------------|--------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Post procedural haemorrhage subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Procedural pain subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Skin laceration subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Subcutaneous haematoma subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Subdural haematoma subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Sunburn subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Synovial rupture subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Transfusion reaction subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Cardiac disorders | | | |
| Atrial enlargement subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Atrial fibrillation subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Pericardial effusion subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 1 / 1 (100.00%) 1 |

| | | | |
|------------------------------|----------------|----------------|-----------------|
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Burning sensation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 7 (28.57%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 3 | 1 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Taste disorder | | | |

| | | | |
|--|--------------------|--------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Coagulopathy | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhagic diathesis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymph node pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |

| | | | |
|-----------------------------|----------------|----------------|---------------|
| Ear and labyrinth disorders | | | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eye disorders | | | |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye inflammation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lacrimation increased | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal distension | | | |

| | | | |
|----------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cheilitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |

| | | | |
|-----------------------------|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival hypertrophy | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 7 (28.57%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Oesophageal fistula | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral blood blister | | | |

| | | | |
|--|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral disorder | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tongue haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hepatobiliary disorders | | | |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blister | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood blister | | | |

| | | | |
|-----------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema multiforme | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail disorder | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Palmar erythema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash macular | | | |

| | | | |
|--|--------------------|---------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Rash erythematous subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 |
| Skin ulcer subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 |
| Skin lesion subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 1 / 1 (100.00%) 1 |
| Skin irritation subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 2 / 7 (28.57%) 2 | 0 / 1 (0.00%) 0 |
| Vitiligo subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Haematuria subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Nocturia subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hypothyroidism subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|-----------------------------|----------------|----------------|---------------|
| Arthralgia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chondrocalcinosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infections and infestations | | | |
| Actinomycosis | | | |

| | | | |
|-----------------------------|----------------|----------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Catheter site cellulitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onychomycosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Osteomyelitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |

| | | | |
|------------------------------------|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular device infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---------------------|---------------------|--------------------|
| Hypoalbuminaemia subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 |
| Hypocalcaemia subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hypoglycaemia subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hypokalaemia subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hypomagnesaemia subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Hyponatraemia subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 1 / 7 (14.29%) 2 | 0 / 1 (0.00%) 0 |
| Hypophosphataemia subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 |
| Iron deficiency subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |

| Non-serious adverse events | Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine | Group C: Combination Therapy; INCB059872 4 mg QD + ATRA | Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab |
|--|--|---|---|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 7 / 7 (100.00%) | 1 / 1 (100.00%) | 6 / 6 (100.00%) |
| Vascular disorders Haematoma subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Hypertension subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 |

| | | | |
|--|---------------------|--------------------|---------------------|
| Hypotension subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| General disorders and administration site conditions | | | |
| Asthenia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Axillary pain subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Chest discomfort subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Chest pain subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 |
| Chills subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Face oedema subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Fatigue subjects affected / exposed occurrences (all) | 3 / 7 (42.86%) 3 | 0 / 1 (0.00%) 0 | 5 / 6 (83.33%) 6 |
| Gait disturbance subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Hernia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Influenza like illness subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 2 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Injection site erythema | | | |

| | | | |
|---|----------------|---------------|---------------|
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Oedema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Breast pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast tenderness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |

| | | | |
|-----------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 2 / 6 (33.33%) |
| occurrences (all) | 1 | 0 | 4 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 1 (100.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hiccups | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngeal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pulmonary oedema | | | |

| | | | |
|--|---------------------|--------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Pulmonary hypertension subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 |
| Wheezing subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Delirium subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Depression subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Insomnia subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Investigations Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Aspartate aminotransferase increased subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Blood alkaline phosphatase increased | | | |

| | | | |
|--|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood thyroid stimulating hormone | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood triglycerides increased | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood urea increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 3 |
| Platelet count increased | | | |

| | | | |
|--|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prothrombin time prolonged | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Troponin increased | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Troponin I increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 1 (0.00%) | 2 / 6 (33.33%) |
| occurrences (all) | 2 | 0 | 2 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Subcutaneous haematoma | | | |

| | | | |
|------------------------------|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Subdural haematoma | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sunburn | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Synovial rupture | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transfusion reaction | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial enlargement | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nervous system disorders | | | |
| Burning sensation | | | |

| | | | |
|--------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 1 (100.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Taste disorder | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 2 / 6 (33.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Coagulopathy | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |

| | | | |
|------------------------------|----------------|---------------|----------------|
| Haemorrhagic diathesis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 5 / 7 (71.43%) | 0 / 1 (0.00%) | 3 / 6 (50.00%) |
| occurrences (all) | 12 | 0 | 6 |
| Ear and labyrinth disorders | | | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vertigo | | | |

| | | | |
|--|---------------------|--------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 |
| Eye disorders | | | |
| Conjunctival haemorrhage subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Eye irritation subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Eye inflammation subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 |
| Lacrimation increased subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Vision blurred subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Vitreous floaters subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Abdominal distension subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Abdominal pain subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 |
| Abdominal pain lower subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Abdominal pain upper | | | |

| | | | |
|----------------------------------|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cheilitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 5 / 7 (71.43%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 5 | 0 | 1 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 2 / 6 (33.33%) |
| occurrences (all) | 1 | 0 | 2 |
| Dry mouth | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Flatulence | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gingival hypertrophy | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival pain | | | |

| | | | |
|-----------------------------|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 5 | 0 | 1 |
| Oesophageal fistula | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral blood blister | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oral disorder | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Rectal haemorrhage | | | |

| | | | |
|--|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| Toothache | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tongue haematoma | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 3 | 0 | 1 |
| Hepatobiliary disorders | | | |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blister | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood blister | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 1 (100.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema multiforme | | | |

| | | | |
|-----------------------------|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail disorder | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palmar erythema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 2 / 6 (33.33%) |
| occurrences (all) | 1 | 0 | 2 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin ulcer | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin lesion | | | |

| | | | |
|---|---------------------|--------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Skin irritation subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Vitiligo subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 |
| Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Haematuria subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Nocturia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 |
| Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Hypothyroidism subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 | 3 / 6 (50.00%) 4 |
| Arthritis subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Back pain subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 |
| Chondrocalcinosis | | | |

| | | | |
|-----------------------------|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 2 / 6 (33.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Neck pain | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Infections and infestations | | | |
| Actinomycosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 2 |
| Catheter site cellulitis | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|----------------|---------------|----------------|
| Fungal infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Gingivitis | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nail infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Onychomycosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Osteomyelitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 2 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---------------------|--------------------|---------------------|
| Vascular device infection subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Decreased appetite subjects affected / exposed occurrences (all) | 2 / 7 (28.57%) 2 | 0 / 1 (0.00%) 0 | 3 / 6 (50.00%) 3 |
| Hypercalcaemia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Hyperglycaemia subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Hyperkalaemia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Hypertriglyceridaemia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Hyperuricaemia subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Hypoalbuminaemia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Hypocalcaemia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Hypoglycaemia subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 | 0 / 6 (0.00%) 0 |
| Hypokalaemia | | | |

| | | | |
|-----------------------------|----------------|---------------|----------------|
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Iron deficiency | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 1 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|---|
| 19 January 2016 | The primary purpose of Amendment 1 was to delete combination therapy from the study design, refine exclusion criteria, add to the prohibited medication list, increase dose-limiting toxicity language, improve language for restarting study drug and at what increments, and add stopping rules. |
| 28 July 2016 | The primary purpose of this amendment was to update the language in the inclusion and exclusion criteria to provide more clarity, to provide additional language regarding different regimens to be explored in this study, and to update Tables 1 through 5. |
| 22 September 2017 | The primary purpose of this amendment was to add dose-finding and expansion cohorts to evaluate INCB059872 in combination with select conventional care treatment regimens in participants with select advanced malignancies and to update aspects of the monotherapy design based on emerging data from the current study. |
| 06 November 2017 | The primary purpose of this amendment was to update the selected doses for monotherapy expansion in Part 2, update the starting doses of INCB059872 in Part 3, clarify dose-limiting toxicity (DLT) evaluability criteria, add early stopping rules for futility in Part 4, adjust the endpoints, revise the eligibility criteria for Cohorts D and D1, add an internal safety committee, and remove references to a pharmacologically active dose. |
| 30 July 2018 | The primary purpose of this amendment was to update and add treatment modification guidance for serious adverse events (SAEs) with suspected causal relationship to study drug. |
| 16 April 2019 | The primary purpose of this amendment was to update Treatment Group D to include myelodysplastic syndrome (MDS) participants, update dose interruption and modification guidance, update inclusion criteria, and update the schedule of assessments for myelofibrosis (MF) participants. |
| 13 June 2019 | The primary purpose of this amendment was to include additional safety monitoring and modify the inclusion criteria for MDS participants in Treatment Group D for Parts 3 and 4 of the Protocol. |
| 15 June 2020 | The primary purpose of this amendment was to add a principal coordinating investigator and remove the exploratory endpoint of overall survival. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was terminated by the sponsor due to a strategic business decision.

Notes: