# Clinical trial results:
# An Open-Label, Multicenter, Phase II Study to Evaluate the Therapeutic Activity of Simlukafusp Alfa (RO6874281), an Immunocytokine, Consisting of Interleukin-2 Variant (IL-2v) Targeting Fibroblast Activation Protein- (FAP), in Combination with Atezolizumab (Anti-PD-L1), Administered Intravenously, in Participants with Advanced and/or Metastatic Solid Tumors

## Summary

| | |
|---|---|
| EudraCT number | 2017-003182-94 |
| Trial protocol | GB ES BE PL DE FR |
| Global end of trial date | 30 December 2021 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 08 January 2023 |
| First version publication date | 08 January 2023 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | BP40234 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03386721 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | F. Hoffmann-La Roche AG |
| Sponsor organisation address | Grenzacherstrasse 124, Basel, Switzerland, CH-4070 |
| Public contact | F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 +41 616878333, global.trial_information@roche.com |
| Scientific contact | F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 +41 616878333, global.trial_information@roche.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 | 30 December 2021 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 30 December 2021 |
| Was the trial ended prematurely? | Yes |

Notes:

## General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the antitumor activity of simlukafusp alfa in combination with atezolizumab in participants with advanced and/or metastatic solid tumors. The main focus of this study was on participants with non−small cell lung cancer (NCSLC) and participants with squamous cell carcinoma (SCC) of the Head and Neck (HNSCC), esophagus (ESCC) and cervix (CSCC).

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 19 February 2018 |
| 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 | Belgium: 18 |
| Country: Number of subjects enrolled | France: 29 |
| Country: Number of subjects enrolled | Germany: 1 |
| Country: Number of subjects enrolled | Israel: 9 |
| Country: Number of subjects enrolled | Korea, Republic of: 19 |
| Country: Number of subjects enrolled | New Zealand: 8 |
| Country: Number of subjects enrolled | Poland: 19 |
| Country: Number of subjects enrolled | Russian Federation: 4 |
| Country: Number of subjects enrolled | Singapore: 7 |
| Country: Number of subjects enrolled | Spain: 78 |
| Country: Number of subjects enrolled | Switzerland: 2 |
| Country: Number of subjects enrolled | Taiwan: 10 |
| Country: Number of subjects enrolled | Turkey: 36 |
| Country: Number of subjects enrolled | United Kingdom: 14 |
| Country: Number of subjects enrolled | United States: 2 |
| Worldwide total number of subjects | 256 |
| EEA total number of subjects | 145 |

Notes:

| Subjects enrolled per age group | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 182 |
| From 65 to 84 years | 74 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Participants took part in the study at 42 investigative sites in Belgium, France, Germany, Israel, Korea, New Zealand, Poland, Russia, Singapore, Spain, Switzerland, Taiwan, Turkey, United Kingdom, USA from 19 February 2018 to 30 December 2021.

### Pre-assignment

Screening details:

A total of 256 participants were enrolled. 95 in NCSLC cohorts [Part I: A,B,D,F&Part II: E]; 161 in SCC cohorts (78 in HNSCC [Part III:G,H,K], 35 in ESCC [Part 3: I&M], & 48 in CSCC [Part III:J&N]) received simlukafusp alfa & atezolizumab.No participants were enrolled in Cohorts C&L as emerging data didn't lead to the need to open these cohorts.

### 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** | NSCLC: Part I Cohort A (QW/Q2W) |

Arm description:

Checkpoint Inhibitor (CPI)-naïve participants with NSCLC, received simlukafusp alfa, 10 milligrams (mg), intravenous (IV) infusion, once weekly (QW) for the first 4 weeks, and every 2 weeks (Q2W) until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months.

| | |
|---|---|
| **Arm title** | NSCLC: Part I Cohort B (QW/Q2W) |

Arm description:

CPI-experienced participants with NSCLC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months.

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

| | |
|---|---|
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months.

| | |
|---|---|
| **Arm title** | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) |

Arm description:

CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months.

| | |
|---|---|
| **Arm title** | NSCLC: Part I Cohort D, Arm 2 (Q3W) |

Arm description:

CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel received simlukafusp alfa, 10 mg, IV infusion once in 3 weeks (Q3W) in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 5.4 months.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal

of consent, or for a maximum of 5.4 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 5.4 months.

| | |
|---|---|
| **Arm title** | NSCLC: Part I Cohort D, Arm 3 (Q3W) |

Arm description:

CPI-experienced participants with NSCLC who were previously treated with platinum-containing regimen and docetaxel received a gemcitabine, IV infusion as per approved protocol. Participants who had documented radiographic disease progression during or after treatment with gemcitabine received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 1.3 months.

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Gemcitabine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Gemcitabine, IV infusion administered as per approved protocol.

| | |
|---|---|
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 1.3 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 1.3 months.

| | |
|---|---|
| **Arm title** | NSCLC: Part I Cohort F (Q3W) |

Arm description:

CPI-experienced, docetaxel naive participants with NSCLC who experienced disease progression during or after treatment with a platinum-containing regimen received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 26 months.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 26 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 26 months.

| | |
|---|---|
| **Arm title** | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) |

Arm description:

NSCLC participants without prior treatment for metastatic disease and with high programmed death-ligand 1 (PD-L1) expression levels, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months.

| | |
|---|---|
| **Arm title** | NSCLC: Part II Cohort E, Arm 2 (Q3W) |

Arm description:

NSCLC participants without prior treatment for metastatic disease and with high PD-L1 expression levels, received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 18.6 months.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 18.6 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |

| | |
|---|---|
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 18.6 months.

| | |
|---|---|
| **Arm title** | SCCHN: Part III Cohort G (Q3W) |

Arm description:

CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.6 months.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.6 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.6 months.

| | |
|---|---|
| **Arm title** | SCCHN: Part III Cohort H (Q3W) |

Arm description:

CPI-experienced participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 10.3 months.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 10.3 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 10.3 months.

| | |
|---|---|
| **Arm title** | ESCC: Part III Cohort I (Q3W) |

Arm description:

CPI-naïve participants with ESCC who were previously treated with standard therapy received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W

until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 30.5 months.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 30.5 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 30.5 months.

| | |
|---|---|
| **Arm title** | CSCC: Part III Cohort J (Q3W) |

Arm description:

CPI-naïve participants with CSCC who were previously treated with standard therapy, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 28.8 months.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 28.8 months.

| | |
|---|---|
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 28.8 months.

| | |
|---|---|
| **Arm title** | SCCHN: Part III Cohort K (QW/Q2W) |

Arm description:

CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months.

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

| | |
|---|---|
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion, Solution for infusion |
| Routes of administration | Intravenous use, Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months

| | |
|---|---|
| **Arm title** | ESCC: Part III Cohort M (QW/Q2W) |

Arm description:

Participants with ESCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion, Solution for infusion |
| Routes of administration | Intravenous use, Intravenous use |

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months

| | |
|---|---|
| **Arm title** | CSCC: Part III Cohort N (QW/Q2W) |

Arm description:

Participants with CSCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Atezolizumab |
| Investigational medicinal product code | RO5541267 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal

of consent, or for a maximum of 0.68 months.

| | |
|---|---|
| Investigational medicinal product name | Simlukafusp alfa |
| Investigational medicinal product code | RO6874281 |
| Other name | FAP-IL2v active |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months

| **Number of subjects in period 1** | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) |
|---|---|---|---|
| Started | 26 | 32 | 3 |
| Completed | 4 | 1 | 0 |
| Not completed | 22 | 31 | 3 |
| Consent withdrawn by subject | 1 | 2 | - |
| Death | 12 | 21 | 2 |
| Progressive Disease | - | - | 1 |
| Site Terminated by Sponsor | 5 | 5 | - |
| Symptomatic Deterioration | - | - | - |
| Lost to follow-up | 1 | 3 | - |
| Reason not specified | 3 | - | - |

| **Number of subjects in period 1** | NSCLC: Part I Cohort D, Arm 2 (Q3W) | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) |
|---|---|---|---|
| Started | 5 | 2 | 22 |
| Completed | 0 | 0 | 1 |
| Not completed | 5 | 2 | 21 |
| Consent withdrawn by subject | - | - | - |
| Death | 5 | 1 | 12 |
| Progressive Disease | - | - | 1 |
| Site Terminated by Sponsor | - | 1 | 3 |
| Symptomatic Deterioration | - | - | - |
| Lost to follow-up | - | - | 2 |
| Reason not specified | - | - | 3 |

| **Number of subjects in period 1** | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) | SCCHN: Part III Cohort G (Q3W) |
|---|---|---|---|
| Started | 3 | 2 | 23 |
| Completed | 0 | 0 | 1 |
| Not completed | 3 | 2 | 22 |
| Consent withdrawn by subject | - | - | 2 |
| Death | 1 | 1 | 12 |

| | | | |
|---|---|---|---|
| Progressive Disease | - | - | 2 |
| Site Terminated by Sponsor | - | 1 | 4 |
| Symptomatic Deterioration | - | - | 1 |
| Lost to follow-up | 1 | - | 1 |
| Reason not specified | 1 | - | - |

| **Number of subjects in period 1** | SCCHN: Part III Cohort H (Q3W) | ESCC: Part III Cohort I (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|
| Started | 30 | 33 | 47 |
| Completed | 0 | 2 | 6 |
| Not completed | 30 | 31 | 41 |
| Consent withdrawn by subject | 1 | 3 | 2 |
| Death | 20 | 21 | 21 |
| Progressive Disease | 1 | 1 | - |
| Site Terminated by Sponsor | 5 | 3 | 11 |
| Symptomatic Deterioration | - | - | 1 |
| Lost to follow-up | 2 | 1 | - |
| Reason not specified | 1 | 2 | 6 |

| **Number of subjects in period 1** | SCCHN: Part III Cohort K (QW/Q2W) | ESCC: Part III Cohort M (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) |
|---|---|---|---|
| Started | 25 | 2 | 1 |
| Completed | 0 | 0 | 0 |
| Not completed | 25 | 2 | 1 |
| Consent withdrawn by subject | 3 | - | - |
| Death | 14 | 2 | 1 |
| Progressive Disease | 1 | - | - |
| Site Terminated by Sponsor | 6 | - | - |
| Symptomatic Deterioration | - | - | - |
| Lost to follow-up | - | - | - |
| Reason not specified | 1 | - | - |

## Baseline characteristics

### Reporting groups

| Reporting group title | NSCLC: Part I Cohort A (QW/Q2W) |
|---|---|

Reporting group description:

Checkpoint Inhibitor (CPI)-naïve participants with NSCLC, received simlukafusp alfa, 10 milligrams (mg), intravenous (IV) infusion, once weekly (QW) for the first 4 weeks, and every 2 weeks (Q2W) until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months.

| Reporting group title | NSCLC: Part I Cohort B (QW/Q2W) |
|---|---|

Reporting group description:

CPI-experienced participants with NSCLC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months.

| Reporting group title | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) |
|---|---|

Reporting group description:

CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months.

| Reporting group title | NSCLC: Part I Cohort D, Arm 2 (Q3W) |
|---|---|

Reporting group description:

CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel received simlukafusp alfa, 10 mg, IV infusion once in 3 weeks (Q3W) in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 5.4 months.

| Reporting group title | NSCLC: Part I Cohort D, Arm 3 (Q3W) |
|---|---|

Reporting group description:

CPI-experienced participants with NSCLC who were previously treated with platinum-containing regimen and docetaxel received a gemcitabine, IV infusion as per approved protocol. Participants who had documented radiographic disease progression during or after treatment with gemcitabine received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 1.3 months.

| Reporting group title | NSCLC: Part I Cohort F (Q3W) |
|---|---|

Reporting group description:

CPI-experienced, docetaxel naive participants with NSCLC who experienced disease progression during or after treatment with a platinum-containing regimen received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 26 months.

| Reporting group title | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) |
|---|---|

Reporting group description:

NSCLC participants without prior treatment for metastatic disease and with high programmed death-ligand 1 (PD-L1) expression levels, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months.

| Reporting group title | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|

Reporting group description:

NSCLC participants without prior treatment for metastatic disease and with high PD-L1 expression levels, received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 18.6 months.

| Reporting group title | SCCHN: Part III Cohort G (Q3W) |
|---|---|

Reporting group description:

CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.6 months.

| Reporting group title | SCCHN: Part III Cohort H (Q3W) |
|---|---|

Reporting group description:

CPI-experienced participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 10.3 months.

| Reporting group title | ESCC: Part III Cohort I (Q3W) |
|---|---|

Reporting group description:

CPI-naïve participants with ESCC who were previously treated with standard therapy received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 30.5 months.

| Reporting group title | CSCC: Part III Cohort J (Q3W) |
|---|---|

Reporting group description:

CPI-naïve participants with CSCC who were previously treated with standard therapy, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 28.8 months.

| Reporting group title | SCCHN: Part III Cohort K (QW/Q2W) |
|---|---|

Reporting group description:

CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months.

| Reporting group title | ESCC: Part III Cohort M (QW/Q2W) |
|---|---|

Reporting group description:

Participants with ESCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months.

| Reporting group title | CSCC: Part III Cohort N (QW/Q2W) |
|---|---|

Reporting group description:

Participants with CSCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months.

| **Reporting group values** | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) |
|---|---|---|---|
| Number of subjects | 26 | 32 | 3 |
| Age categorical<br>Units: Subjects | | | |

| | | | |
|---|---|---|---|
| Age Continuous<br>Units: years | | | |
| arithmetic mean | 58.0 | 59.8 | 63.7 |
| standard deviation | ± 10.5 | ± 9.9 | ± 3.8 |

| | | | |
|---|---|---|---|
| Sex: Female, Male<br>Units: participants | | | |
| Female | 10 | 10 | 1 |
| Male | 16 | 22 | 2 |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 1 | 0 |
| Not Hispanic or Latino | 23 | 28 | 3 |
| Not Stated | 1 | 2 | 0 |
| Unknown | 2 | 1 | 0 |
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 9 | 5 | 0 |
| Native Hawaiian or Other Pacific Islander | 2 | 0 | 0 |
| Black or African American | 0 | 1 | 0 |
| White | 15 | 26 | 3 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |

| **Reporting group values** | NSCLC: Part I Cohort D, Arm 2 (Q3W) | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) |
|---|---|---|---|
| Number of subjects | 5 | 2 | 22 |
| Age categorical<br>Units: Subjects | | | |
| Age Continuous<br>Units: years | | | |
| arithmetic mean | 65.6 | 63.5 | 57.4 |
| standard deviation | ± 4.3 | ± 4.9 | ± 8.9 |
| Sex: Female, Male<br>Units: participants | | | |
| Female | 0 | 1 | 11 |
| Male | 5 | 1 | 11 |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 1 |
| Not Hispanic or Latino | 4 | 2 | 20 |
| Not Stated | 1 | 0 | 1 |
| Unknown | 0 | 0 | 0 |
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 0 | 5 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 5 | 2 | 17 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |

| Reporting group values | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) | SCCHN: Part III Cohort G (Q3W) |
|---|---|---|---|
| Number of subjects | 3 | 2 | 23 |
| Age categorical | | | |
| Units: Subjects | | | |
| Age Continuous | | | |
| Units: years | | | |
| arithmetic mean | 56.7 | 68.0 | 55.7 |
| standard deviation | ± 0.6 | ± 2.8 | ± 12.8 |
| Sex: Female, Male | | | |
| Units: participants | | | |
| Female | 1 | 0 | 5 |
| Male | 2 | 2 | 18 |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 3 | 2 | 22 |
| Not Stated | 0 | 0 | 1 |
| Unknown | 0 | 0 | 0 |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 1 | 0 | 3 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 1 |
| Black or African American | 0 | 0 | 0 |
| White | 2 | 2 | 19 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |

| Reporting group values | SCCHN: Part III Cohort H (Q3W) | ESCC: Part III Cohort I (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|
| Number of subjects | 30 | 33 | 47 |
| Age categorical | | | |
| Units: Subjects | | | |
| Age Continuous | | | |
| Units: years | | | |
| arithmetic mean | 58.8 | 63.1 | 51.3 |
| standard deviation | ± 8.2 | ± 9.6 | ± 11.2 |
| Sex: Female, Male | | | |
| Units: participants | | | |
| Female | 7 | 10 | 47 |
| Male | 23 | 23 | 0 |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 1 | 0 | 0 |
| Not Hispanic or Latino | 21 | 27 | 33 |
| Not Stated | 7 | 4 | 9 |
| Unknown | 1 | 2 | 5 |

| | | | |
|---|---|---|---|
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 5 | 6 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 1 |
| Black or African American | 1 | 0 | 0 |
| White | 16 | 22 | 33 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 8 | 5 | 13 |

| **Reporting group values** | SCCHN: Part III Cohort K (QW/Q2W) | ESCC: Part III Cohort M (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) |
|---|---|---|---|
| Number of subjects | 25 | 2 | 1 |
| Age categorical<br>Units: Subjects | | | |
| Age Continuous<br>Units: years | | | |
| arithmetic mean | 55.8 | 67.0 | 49.0 |
| standard deviation | ± 11.7 | ± 15.6 | ± 99999 |
| Sex: Female, Male<br>Units: participants | | | |
| Female | 6 | 0 | 1 |
| Male | 19 | 2 | 0 |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 23 | 1 | 1 |
| Not Stated | 2 | 1 | 0 |
| Unknown | 0 | 0 | 0 |
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 5 | 1 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 18 | 0 | 1 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 2 | 1 | 0 |

| **Reporting group values** | Total | | |
|---|---|---|---|
| Number of subjects | 256 | | |
| Age categorical<br>Units: Subjects | | | |
| Age Continuous<br>Units: years | | | |
| arithmetic mean | | | |
| standard deviation | - | | |

| | | | |
|---|---|---|---|
| Sex: Female, Male<br>Units: participants | | | |
| Female | 110 | | |
| Male | 146 | | |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| Hispanic or Latino | 3 | | |
| Not Hispanic or Latino | 213 | | |
| Not Stated | 29 | | |
| Unknown | 11 | | |
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native | 0 | | |
| Asian | 40 | | |
| Native Hawaiian or Other Pacific Islander | 4 | | |
| Black or African American | 2 | | |
| White | 181 | | |
| More than one race | 0 | | |
| Unknown or Not Reported | 29 | | |

### End points reporting groups

| Reporting group title | NSCLC: Part I Cohort A (QW/Q2W) |
|---|---|

Reporting group description:

Checkpoint Inhibitor (CPI)-naïve participants with NSCLC, received simlukafusp alfa, 10 milligrams (mg), intravenous (IV) infusion, once weekly (QW) for the first 4 weeks, and every 2 weeks (Q2W) until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months.

| Reporting group title | NSCLC: Part I Cohort B (QW/Q2W) |
|---|---|

Reporting group description:

CPI-experienced participants with NSCLC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months.

| Reporting group title | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) |
|---|---|

Reporting group description:

CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months.

| Reporting group title | NSCLC: Part I Cohort D, Arm 2 (Q3W) |
|---|---|

Reporting group description:

CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel received simlukafusp alfa, 10 mg, IV infusion once in 3 weeks (Q3W) in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 5.4 months.

| Reporting group title | NSCLC: Part I Cohort D, Arm 3 (Q3W) |
|---|---|

Reporting group description:

CPI-experienced participants with NSCLC who were previously treated with platinum-containing regimen and docetaxel received a gemcitabine, IV infusion as per approved protocol. Participants who had documented radiographic disease progression during or after treatment with gemcitabine received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 1.3 months.

| Reporting group title | NSCLC: Part I Cohort F (Q3W) |
|---|---|

Reporting group description:

CPI-experienced, docetaxel naive participants with NSCLC who experienced disease progression during or after treatment with a platinum-containing regimen received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 26 months.

| Reporting group title | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) |
|---|---|

Reporting group description:

NSCLC participants without prior treatment for metastatic disease and with high programmed death-ligand 1 (PD-L1) expression levels, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months.

| Reporting group title | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|

Reporting group description:

NSCLC participants without prior treatment for metastatic disease and with high PD-L1 expression levels, received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 18.6 months.

| Reporting group title | SCCHN: Part III Cohort G (Q3W) |
|---|---|

Reporting group description:

CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.6 months.

| Reporting group title | SCCHN: Part III Cohort H (Q3W) |
|---|---|

Reporting group description:

CPI-experienced participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 10.3 months.

| Reporting group title | ESCC: Part III Cohort I (Q3W) |
|---|---|

Reporting group description:

CPI-naïve participants with ESCC who were previously treated with standard therapy received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 30.5 months.

| Reporting group title | CSCC: Part III Cohort J (Q3W) |
|---|---|

Reporting group description:

CPI-naïve participants with CSCC who were previously treated with standard therapy, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 28.8 months.

| Reporting group title | SCCHN: Part III Cohort K (QW/Q2W) |
|---|---|

Reporting group description:

CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months.

| Reporting group title | ESCC: Part III Cohort M (QW/Q2W) |
|---|---|

Reporting group description:

Participants with ESCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months.

| Reporting group title | CSCC: Part III Cohort N (QW/Q2W) |
|---|---|

Reporting group description:

Participants with CSCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months.

## Primary: Percentage of Participants with Objective Response Rate (ORR) According to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1

| End point title | Percentage of Participants with Objective Response Rate (ORR) According to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1[1] |
|---|---|

End point description:

ORR was defined as the percentage of participants with observed tumor response of complete response (CR), or partial response (PR) determined according to RECIST version 1.1. CR was defined as the disappearance of all target lesions with reduction in target/non-target pathological lymph nodes to <10 millimeters (mm). PR was defined as at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. The percentages of participants are rounded off to the nearest single decimal point. Response evaluable population included all participants in the safety population who received at least one dose of simlukafusp alfa/atezolizumab and who had at least one baseline and one on-study tumor assessment.

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

End point timeframe:

Baseline up to disease progression or study treatment discontinuation (up to 38 months)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As pre specified in the protocol no formal statistical model and no formal hypothesis testing were planned in this for this endpoint.

| **End point values** | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) | NSCLC: Part I Cohort D, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 32 | 3 | 5 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 19.2 (8.51 to 37.88) | 6.3 (1.73 to 20.15) | 0 (0.00 to 56.15) | 0 (0.00 to 43.45) |

| **End point values** | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[2] | 21 | 3 | 2 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | ( to ) | 4.8 (0.85 to 22.67) | 66.7 (20.77 to 93.85) | 50.0 (9.45 to 90.55) |

Notes:

[2] - Participants from this cohort were not included in the Response evaluable population.

| **End point values** | SCCHN: Part III Cohort G (Q3W) | SCCHN: Part III Cohort H (Q3W) | ESCC: Part III Cohort I (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 22 | 28 | 32 | 44 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 18.2 (7.31 to 38.52) | 3.6 (0.63 to 17.71) | 21.9 (11.02 to 38.75) | 27.3 (16.35 to 41.85) |

| **End point values** | SCCHN: Part III Cohort K (QW/Q2W) | ESCC: Part III Cohort M (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 25 | 2 | 1 | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 4.0 (0.71 to 19.54) | 0 (0.00 to 65.76) | 0 (0.00 to 79.35) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants with Disease Control Rate (DCR) Determined According to RECIST Version 1.1

| End point title | Percentage of Participants with Disease Control Rate (DCR) Determined According to RECIST Version 1.1 |
|---|---|

End point description:

DCR: percentage of participants with observed tumor response of CR, PR or stable disease (SD) as per RECIST v 1.1. CR: disappearance of all target lesions with reduction in target/non-target pathological lymph nodes to <10 mm. PR = at least a 30% decrease in the sum of diameters of target lesions, with reference to baseline sum diameters. SD: neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease (PD). PD = at least a 20% decrease in the sum of diameters of target lesions, with reference to smallest sum on study including baseline (nadir). The percentages of participants are rounded off to the nearest single decimal point. Response evaluable population = all participants in the safety population who received at least one dose of simlukafusp alfa/atezolizumab and who had at least one baseline and one on-study tumor assessment.

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

End point timeframe:

Baseline up to disease progression or study treatment discontinuation (up to 38 months)

| End point values | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) | NSCLC: Part I Cohort D, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 32 | 3 | 5 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 53.8 (35.46 to 71.24) | 62.5 (45.25 to 77.07) | 0 (0.00 to 56.15) | 20.0 (3.62 to 62.45) |

| End point values | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[3] | 21 | 3 | 2 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | ( to ) | 57.1 (36.55 to 75.53) | 66.7 (20.77 to 93.85) | 50.0 (9.45 to 90.55) |

Notes:

[3] - Participants form this cohort were not included in the Response evaluable population

| End point values | SCCHN: Part III Cohort G (Q3W) | SCCHN: Part III Cohort H (Q3W) | ESCC: Part III Cohort I (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 22 | 28 | 32 | 44 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 50.0 (30.72 to 69.28) | 14.3 (5.70 to 31.49) | 43.8 (28.17 to 60.67) | 68.2 (53.44 to 80.00) |

| End point values | SCCHN: Part III Cohort K (QW/Q2W) | ESCC: Part III Cohort M (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 25 | 2 | 1 | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 36.0 (20.25 to 55.48) | 50.0 (9.45 to 90.55) | 0 (0.00 to 79.35) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Duration of Response (DoR) According to RECIST Version 1.1

| End point title | Duration of Response (DoR) According to RECIST Version 1.1 |
|---|---|

End point description:

DoR was determined for participants who had a best overall response of CR or PR. CR = disappearance of all target lesions with reduction in target/non-target pathological lymph nodes to < 10 mm. PR = at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. DoR = time from first occurrence of a documented objective response until the time of documented disease progression or death from any cause during treatment, whichever occurs first. Participants that did not have documented progressive disease or death during the study were censored at the day of the last tumor assessment. Data could not be collected for this endpoint due to premature termination of the study by the sponsor.

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

End point timeframe:

From first occurrence of documented CR or PR up to disease progression or study treatment discontinuation (assessed every 8 weeks after study treatment start for the first year, and every 12 weeks thereafter, up to 38 months)

| End point values | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) | NSCLC: Part I Cohort D, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[4] | 0[5] | 0[6] | 0[7] |
| Units: months | | | | |
| median (confidence interval 95%) | ( to ) | ( to ) | ( to ) | ( to ) |

Notes:

[4] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[5] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[6] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[7] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

| End point values | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|---|---|---|

| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
|---|---|---|---|---|
| Number of subjects analysed | 0[8] | 0[9] | 0[10] | 0[11] |
| Units: months | | | | |
| median (confidence interval 95%) | ( to ) | ( to ) | ( to ) | ( to ) |

Notes:

[8] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[9] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[10] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.
[11] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

| **End point values** | SCCHN: Part III Cohort G (Q3W) | SCCHN: Part III Cohort H (Q3W) | ESCC: Part III Cohort I (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[12] | 0[13] | 0[14] | 0[15] |
| Units: months | | | | |
| median (confidence interval 95%) | ( to ) | ( to ) | ( to ) | ( to ) |

Notes:

[12] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.
[13] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.
[14] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.
[15] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

| **End point values** | SCCHN: Part III Cohort K (QW/Q2W) | ESCC: Part III Cohort M (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0[16] | 0[17] | 0[18] | |
| Units: months | | | | |
| median (confidence interval 95%) | ( to ) | ( to ) | ( to ) | |

Notes:

[16] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.
[17] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.
[18] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Progression-Free Survival (PFS) According to RECIST Version 1.1

| End point title | Progression-Free Survival (PFS) According to RECIST Version 1.1 |
|---|---|

End point description:

PFS was defined as the time from study treatment initiation (Cycle 1 Day 1 [1 cycle=14 days for QW/Q2W cohorts; 1 cycle=21 days for Q3W cohorts]) to the first occurrence of documented disease progression (based on Investigator’s assessment) or death from any cause during treatment, whichever occurs first. Participants that did not have documented progressive disease or death during the study were censored at the day of the last tumor assessment. Here, 99999=Medain and upper limit of 95% CI could not be calculated due to low number of participants with events. 0.99999=Lower limit of 95% CI could not be calculated as only one participant with events was evaluated. 999999=Upper limit of 95% CI could not be calculated as only one participant with events was evaluated. Response evaluable

population included all participants in the safety population who received at least one dose of simlukafusp alfa/atezolizumab and who had at least one baseline and one on-study tumor assessment.

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

End point timeframe:

Study treatment initiation up to disease progression or study treatment discontinuation (up to 38 months)

| **End point values** | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) | NSCLC: Part I Cohort D, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 32 | 3 | 5 |
| Units: months | | | | |
| median (confidence interval 95%) | 3.5 (1.7 to 7.4) | 3.7 (3.1 to 5.2) | 2.0 (1.7 to 99999) | 2.0 (1.9 to 99999) |

| **End point values** | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[19] | 21 | 3 | 2 |
| Units: months | | | | |
| median (confidence interval 95%) | ( to ) | 3.5 (1.9 to 5.5) | 99999 (2.6 to 99999) | 10.5 (1.9 to 99999) |

Notes:

[19] - Participants from this cohort were not included in the Response evaluable population.

| **End point values** | SCCHN: Part III Cohort G (Q3W) | SCCHN: Part III Cohort H (Q3W) | ESCC: Part III Cohort I (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 22 | 28 | 32 | 44 |
| Units: months | | | | |
| median (confidence interval 95%) | 2.5 (1.8 to 5.6) | 1.9 (1.8 to 1.9) | 1.9 (1.8 to 3.7) | 3.7 (3.3 to 9.0) |

| **End point values** | SCCHN: Part III Cohort K (QW/Q2W) | ESCC: Part III Cohort M (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 25 | 2 | 1 | |
| Units: months | | | | |
| median (confidence interval 95%) | 1.9 (1.6 to 3.2) | 2.6 (1.6 to 99999) | 1.9 (0.99999 to 999999) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Overall Survival (OS)

| End point title | Overall Survival (OS) |
|---|---|

End point description:

OS was defined as the time from the first dose of study treatment to the time of death from any cause on study. Participants who were still alive at the time of analysis were censored at the last date known alive. As pre-specified in the protocol, data for OS was to be reported if data was mature at the time of analysis. The data was not reported for this endpoint as data was not matured and sufficient to be analysed during the analysis as the study was terminated prematurely and no safety follow for survival took place.

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

End point timeframe:

From first dose of study treatment up to death due to any cause (up to approximately 47 months)

| End point values | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) | NSCLC: Part I Cohort D, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[20] | 0[21] | 0[22] | 0[23] |
| Units: months | | | | |
| median (confidence interval 95%) | ( to ) | ( to ) | ( to ) | ( to ) |

Notes:

[20] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[21] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[22] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[23] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

| End point values | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[24] | 0[25] | 0[26] | 0[27] |
| Units: months | | | | |
| median (confidence interval 95%) | ( to ) | ( to ) | ( to ) | ( to ) |

Notes:

[24] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[25] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[26] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[27] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

| End point values | SCCHN: Part III Cohort G (Q3W) | SCCHN: Part III Cohort H (Q3W) | ESCC: Part III Cohort I (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[28] | 0[29] | 0[30] | 0[31] |
| Units: months | | | | |
| median (confidence interval 95%) | ( to ) | ( to ) | ( to ) | ( to ) |

Notes:

[28] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[29] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[30] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[31] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

| **End point values** | SCCHN: Part III Cohort K (QW/Q2W) | ESCC: Part III Cohort M (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0[32] | 0[33] | 0[34] | |
| Units: months | | | | |
| median (confidence interval 95%) | ( to ) | ( to ) | ( to ) | |

Notes:

[32] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[33] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[34] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants with Adverse Events (AEs)

| End point title | Percentage of Participants with Adverse Events (AEs) |
|---|---|

End point description:

An AE is any untoward medical occurrence in a participant or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Safety Population included all participants who received at least one dose of study treatment, whether prematurely withdrawn from the study or not.

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

End point timeframe:

Baseline up to end of the study (up to approximately 47 months)

| **End point values** | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) | NSCLC: Part I Cohort D, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 32 | 3 | 5 |
| Units: percentage of participants | | | | |
| number (not applicable) | 100 | 100 | 100 | 100 |

| **End point values** | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 2 | 22 | 3 | 2 |
| Units: percentage of participants | | | | |

| | | | | |
|---|---|---|---|---|
| number (not applicable) | 100 | 100 | 100 | 100 |

| End point values | SCCHN: Part III Cohort G (Q3W) | SCCHN: Part III Cohort H (Q3W) | ESCC: Part III Cohort I (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 23 | 30 | 33 | 47 |
| Units: percentage of participants | | | | |
| number (not applicable) | 100 | 100 | 100 | 100 |

| End point values | SCCHN: Part III Cohort K (QW/Q2W) | ESCC: Part III Cohort M (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 25 | 2 | 1 | |
| Units: percentage of participants | | | | |
| number (not applicable) | 100 | 100 | 100 | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants by Programmed Death-Ligand 1 (PD-L1) Status According to Immunohistochemical Methods

| End point title | Percentage of Participants by Programmed Death-Ligand 1 (PD-L1) Status According to Immunohistochemical Methods |
|---|---|

End point description:

Data was not collected for this endpoint post-baseline as baseline data was not matured and sufficient to analyse PD-L1 impact.

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

End point timeframe:

Baseline

| End point values | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) | NSCLC: Part I Cohort D, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[35] | 0[36] | 0[37] | 0[38] |
| Units: percentage of participants | | | | |

Notes:

[35] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[36] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[37] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[38] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

| End point values | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[39] | 0[40] | 0[41] | 0[42] |
| Units: percentage of participants | | | | |

Notes:

[39] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[40] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[41] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[42] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

| End point values | SCCHN: Part III Cohort G (Q3W) | SCCHN: Part III Cohort H (Q3W) | ESCC: Part III Cohort I (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[43] | 0[44] | 0[45] | 0[46] |
| Units: percentage of participants | | | | |

Notes:

[43] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[44] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[45] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[46] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

| End point values | SCCHN: Part III Cohort K (QW/Q2W) | ESCC: Part III Cohort M (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0[47] | 0[48] | 0[49] | |
| Units: percentage of participants | | | | |

Notes:

[47] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[48] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[49] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Density of Cluster of Differentiation (CD) 8 Positive (CD8+) Cells According to Immunohistochemical Methods

| End point title | Change from Baseline in Density of Cluster of Differentiation (CD) 8 Positive (CD8+) Cells According to Immunohistochemical Methods |
|---|---|

End point description:

Data was not collected for this endpoint post-baseline as baseline data was not matured and sufficient to be analysed during analysis.

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

End point timeframe:

Baseline up to 2 months

| End point values | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) | NSCLC: Part I Cohort D, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[50] | 0[51] | 0[52] | 0[53] |
| Units: Cell/mm (2) | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[50] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[51] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[52] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[53] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

| End point values | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[54] | 0[55] | 0[56] | 0[57] |
| Units: Cell/mm (2) | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[54] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[55] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[56] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[57] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

| End point values | SCCHN: Part III Cohort G (Q3W) | SCCHN: Part III Cohort H (Q3W) | ESCC: Part III Cohort I (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[58] | 0[59] | 0[60] | 0[61] |
| Units: Cell/mm (2) | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[58] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[59] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[60] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[61] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

| End point values | SCCHN: Part III Cohort K (QW/Q2W) | ESCC: Part III Cohort M (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0[62] | 0[63] | 0[64] | |
| Units: Cell/mm (2) | | | | |
| arithmetic mean (standard deviation) | () | () | () | |

Notes:

[62] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[63] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[64] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Density of Cluster of Differentiation 3 Negative (CD3-) Perforin Positive Cells According to Immunohistochemical Methods

| End point title | Change from Baseline in Density of Cluster of Differentiation 3 Negative (CD3-) Perforin Positive Cells According to Immunohistochemical Methods |
|---|---|

End point description:

Data was not collected for this endpoint post-baseline as baseline data was not matured and sufficient to be analysed during analysis.

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

End point timeframe:

Baseline up to 2 months

| End point values | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) | NSCLC: Part I Cohort D, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[65] | 0[66] | 0[67] | 0[68] |
| Units: Cell/mm (2) | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[65] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[66] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[67] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[68] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

| End point values | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[69] | 0[70] | 0[71] | 0[72] |
| Units: Cell/mm (2) | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[69] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[70] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[71] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[72] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

| End point values | SCCHN: Part III Cohort G (Q3W) | SCCHN: Part III Cohort H (Q3W) | ESCC: Part III Cohort I (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[73] | 0[74] | 0[75] | 0[76] |
| Units: Cell/mm (2) | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[73] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[74] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[75] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[76] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

| **End point values** | SCCHN: Part III Cohort K (QW/Q2W) | ESCC: Part III Cohort M (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0[77] | 0[78] | 0[79] | |
| Units: Cell/mm (2) | | | | |
| arithmetic mean (standard deviation) | () | () | () | |

Notes:

[77] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[78] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[79] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Density of PD-L1 According to Immunohistochemical Methods

| End point title | Change from Baseline in Density of PD-L1 According to Immunohistochemical Methods |
|---|---|

End point description:

Data was not collected for this endpoint post-baseline as baseline data was not matured and sufficient to analyse PD-L1 impact.

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

End point timeframe:

Baseline up to 2 months

| **End point values** | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) | NSCLC: Part I Cohort D, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[80] | 0[81] | 0[82] | 0[83] |
| Units: Cell/mm (2) | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[80] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[81] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[82] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[83] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

| **End point values** | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[84] | 0[85] | 0[86] | 0[87] |
| Units: Cell/mm (2) | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[84] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[85] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[86] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[87] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

| **End point values** | SCCHN: Part III Cohort G (Q3W) | SCCHN: Part III Cohort H (Q3W) | ESCC: Part III Cohort I (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[88] | 0[89] | 0[90] | 0[91] |
| Units: Cell/mm (2) | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[88] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[89] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[90] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[91] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

| **End point values** | SCCHN: Part III Cohort K (QW/Q2W) | ESCC: Part III Cohort M (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0[92] | 0[93] | 0[94] | |
| Units: Cell/mm (2) | | | | |
| arithmetic mean (standard deviation) | () | () | () | |

Notes:

[92] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[93] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[94] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

## Statistical analyses

No statistical analyses for this end point

## Adverse events information

Timeframe for reporting adverse events:

Baseline up to end of the study (up to approximately 47 months)

Adverse event reporting additional description:

Safety-evaluable population included all participants who received at least one dose of study treatment, whether prematurely withdrawn from the study or not.

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

## Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 23.1 |

## Reporting groups

| | |
|---|---|
| Reporting group title | NSCLC: Part I Cohort A (QW/Q2W) |

Reporting group description:

CPI-naïve participants with NSCLC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months.

| | |
|---|---|
| Reporting group title | NSCLC: Part I Cohort B (QW/Q2W) |

Reporting group description:

CPI-experienced participants with NSCLC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months.

| | |
|---|---|
| Reporting group title | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) |

Reporting group description:

CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months.

| | |
|---|---|
| Reporting group title | NSCLC: Part I Cohort D, Arm 2 (Q3W) |

Reporting group description:

CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 5.4 months.

| | |
|---|---|
| Reporting group title | NSCLC: Part I Cohort D, Arm 3 (Q3W) |

Reporting group description:

CPI-experienced participants with NSCLC who were previously treated with platinum-containing regimen and docetaxel received a gemcitabine, IV infusion as per approved protocol. Participants who had documented radiographic disease progression during or after treatment with gemcitabine received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 1.3 months.

| | |
|---|---|
| Reporting group title | NSCLC: Part I Cohort F (Q3W) |

Reporting group description:

CPI-experienced, docetaxel naive participants with NSCLC who experienced disease progression during or after treatment with a platinum-containing regimen received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 26 months.

| | |
|---|---|
| Reporting group title | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) |

Reporting group description:

NSCLC participants without prior treatment for metastatic disease and with high PD-L1 expression levels, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months.

| Reporting group title | NSCLC: Part II Cohort E, Arm 2 (Q3W) |
|---|---|

Reporting group description:

NSCLC participants without prior treatment for metastatic disease and with high PD-L1 expression levels, received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 18.6 months.

| Reporting group title | CSCC: Part III Cohort J (Q3W) |
|---|---|

Reporting group description:

CPI-naïve participants with CSCC who were previously treated with standard therapy, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 28.8 months.

| Reporting group title | ESCC: Part III Cohort I (Q3W) |
|---|---|

Reporting group description:

CPI-naïve participants with ESCC who were previously treated with standard therapy received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 30.5 months.

| Reporting group title | SCCHN: Part III Cohort G (Q3W) |
|---|---|

Reporting group description:

CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.6 months.

| Reporting group title | SCCHN: Part III Cohort H (Q3W) |
|---|---|

Reporting group description:

CPI-experienced participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 10.3 months.

| Reporting group title | ESCC: Part III Cohort M (QW/Q2W) |
|---|---|

Reporting group description:

Participants with ESCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months.

| Reporting group title | SCCHN: Part III Cohort K (QW/Q2W) |
|---|---|

Reporting group description:

CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months.

| Reporting group title | CSCC: Part III Cohort N (QW/Q2W) |
|---|---|

Reporting group description:

Participants with CSCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months.

| **Serious adverse events** | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 13 / 26 (50.00%) | 25 / 32 (78.13%) | 0 / 3 (0.00%) |
| number of deaths (all causes) | 12 | 21 | 3 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| MALIGNANT NEOPLASM PROGRESSION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TUMOUR HAEMORRHAGE | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| TUMOUR PAIN | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| CAPILLARY LEAK SYNDROME | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEEP VEIN THROMBOSIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EMBOLISM | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOTENSION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 26 (7.69%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 3 / 3 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VASCULITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| MEDICAL DEVICE REMOVAL | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| CHILLS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FACIAL PAIN | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FATIGUE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GENERAL PHYSICAL HEALTH DETERIORATION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GENERALISED OEDEMA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MALAISE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MEDICAL DEVICE SITE HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OEDEMA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PAIN | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PERFORMANCE STATUS DECREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PYREXIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 26 (3.85%) | 4 / 32 (12.50%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 4 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| ANAPHYLACTIC REACTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ANAPHYLACTIC SHOCK | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SYSTEMIC IMMUNE ACTIVATION | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| FEMALE GENITAL TRACT FISTULA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VAGINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| ASPIRATION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| ASTHMA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BRONCHOSPASM | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COUGH | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DYSPNOEA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMOPTYSIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LARYNGEAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PHARYNGEAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PLEURAL EFFUSION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMOTHORAX | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PULMONARY EMBOLISM | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RESPIRATORY FAILURE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| CONFUSIONAL STATE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Product issues | | | |
| DEVICE DISLOCATION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BLOOD BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BLOOD CREATININE INCREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EJECTION FRACTION DECREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HEPATIC ENZYME INCREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LIVER FUNCTION TEST INCREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LYMPHOCYTE COUNT DECREASED | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OXYGEN SATURATION DECREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PLATELET COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TRANSAMINASES INCREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| INCORRECT DOSE ADMINISTERED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 3 / 32 (9.38%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 17 / 17 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MEDICATION ERROR | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POST PROCEDURAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SKIN LACERATION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UROSTOMY COMPLICATION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VASCULAR ACCESS COMPLICATION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders | | | |
| TRACHEO-OESOPHAGEAL FISTULA | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| ATRIAL FIBRILLATION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYOCARDIAL INFARCTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYOCARDITIS | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PERICARDIAL EFFUSION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| AGNOSIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| APHASIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CEREBRAL ISCHAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CEREBROVASCULAR ACCIDENT | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ENCEPHALOPATHY | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EPILEPSY | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NEURALGIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POLYNEUROPATHY | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SYNCOPE | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VOCAL CORD PARALYSIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| **Blood and lymphatic system disorders** | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| **Gastrointestinal disorders** | | | |

| | | | |
|---|---|---|---|
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COLITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTRIC HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| IMMUNE-MEDIATED ENTEROCOLITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LARGE INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MOUTH HAEMORRHAGE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL FISTULA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL STENOSIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PANCREATITIS | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PANCREATITIS ACUTE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PROCTALGIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RECTAL HAEMORRHAGE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SMALL INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UPPER GASTROINTESTINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VOMITING | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| BILE DUCT STENOSIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BILIARY OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLECYSTITIS ACUTE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLELITHIASIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DRUG-INDUCED LIVER INJURY | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HEPATITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HEPATOTOXICITY | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| DERMATITIS ACNEIFORM | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PRURITUS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RASH | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| STEVENS-JOHNSON SYNDROME | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| ACUTE KIDNEY INJURY | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMATURIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYDRONEPHROSIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NEPHRITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PYELOCALIECTASIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RENAL FAILURE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| ADDISON'S DISEASE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| IMMUNE-MEDIATED HYPOPHYSITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|---|---|---|
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYALGIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PATHOLOGICAL FRACTURE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| ABDOMINAL WALL ABSCESS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| APPENDICITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ARTHRITIS BACTERIAL | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ASPERGILLUS INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BACTERAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BACTERIAL INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BRONCHITIS | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CORNEAL INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEVICE RELATED INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ENCEPHALITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ESCHERICHIA INFECTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LYMPH GLAND INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PELVIC INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PERITONEAL ABSCESS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PLEURAL INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 3 / 32 (9.38%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA BACTERIAL | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA NECROTISING | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POSTOPERATIVE WOUND INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PULMONARY SEPSIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SEPSIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SEPTIC SHOCK | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SKIN INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT INFECTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VASCULAR DEVICE INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| HYPERCALCAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOGLYCAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOPHOSPHATAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MALNUTRITION | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TYPE 1 DIABETES MELLITUS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | NSCLC: Part I Cohort D, Arm 2 (Q3W) | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 5 (60.00%) | 2 / 2 (100.00%) | 14 / 22 (63.64%) |
| number of deaths (all causes) | 5 | 1 | 12 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| MALIGNANT NEOPLASM PROGRESSION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TUMOUR HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 | | | |
| CAPILLARY LEAK SYNDROME | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEEP VEIN THROMBOSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EMBOLISM | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VASCULITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| MEDICAL DEVICE REMOVAL | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 | | | |
| CHILLS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FACIAL PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| FATIGUE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 PHYSICAL HEALTH DETERIORATION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GENERALISED OEDEMA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MALAISE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MEDICAL DEVICE SITE HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OEDEMA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OEDEMA PERIPHERAL | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PERFORMANCE STATUS DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| ANAPHYLACTIC REACTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ANAPHYLACTIC SHOCK | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SYSTEMIC IMMUNE ACTIVATION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| FEMALE GENITAL TRACT FISTULA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| VAGINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 | | | |
| ASPIRATION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ASTHMA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BRONCHOSPASM | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COUGH | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMOPTYSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LARYNGEAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PHARYNGEAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMOTHORAX | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 1 / 22 (4.55%) |
| 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 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Product issues | | | |

| | | | |
|---|---|---|---|
| DEVICE DISLOCATION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BLOOD BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BLOOD CREATININE INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EJECTION FRACTION DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 ENZYME INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| LIVER FUNCTION TEST INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LYMPHOCYTE COUNT DECREASED | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 5 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OXYGEN SATURATION DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PLATELET COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TRANSAMINASES INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 | | | |
| INCORRECT DOSE ADMINISTERED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| 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 | 2 / 5 (40.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 4 / 4 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| MEDICATION ERROR | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POST PROCEDURAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 LACERATION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UROSTOMY COMPLICATION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 ACCESS COMPLICATION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders | | | |
| TRACHEO-OESOPHAGEAL FISTULA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYOCARDIAL INFARCTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| MYOCARDITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PERICARDIAL EFFUSION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 | | | |
| AGNOSIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| APHASIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CEREBRAL ISCHAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CEREBROVASCULAR ACCIDENT | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ENCEPHALOPATHY | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EPILEPSY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NEURALGIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POLYNEUROPATHY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VOCAL CORD PARALYSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NEUTROPENIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 UPPER | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 2 (50.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COLITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTRIC HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| IMMUNE-MEDIATED ENTEROCOLITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INTESTINAL OBSTRUCTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LARGE INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL FISTULA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL STENOSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PANCREATITIS ACUTE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PROCTALGIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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%) | 1 / 2 (50.00%) | 0 / 22 (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 |
| SMALL INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| BILE DUCT STENOSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BILIARY OBSTRUCTION | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLECYSTITIS ACUTE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLELITHIASIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DRUG-INDUCED LIVER INJURY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HEPATITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HEPATOTOXICITY | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (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 |
| Skin and subcutaneous tissue disorders | | | |
| DERMATITIS ACNEIFORM | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PRURITUS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RASH | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| STEVENS-JOHNSON SYNDROME | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| ACUTE KIDNEY INJURY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMATURIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYDRONEPHROSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NEPHRITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PYELOCALIECTASIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RENAL FAILURE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 | | | |

| | | | |
|---|---|---|---|
| ADDISON'S DISEASE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| IMMUNE-MEDIATED HYPOPHYSITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 | | | |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYALGIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PATHOLOGICAL FRACTURE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| ABDOMINAL WALL ABSCESS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| APPENDICITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| ARTHRITIS BACTERIAL | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ASPERGILLUS INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BACTERIAL INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CORNEAL INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEVICE RELATED INFECTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ENCEPHALITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ESCHERICHIA INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LYMPH GLAND INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PELVIC INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PERITONEAL ABSCESS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PLEURAL INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 5 (0.00%) | 0 / 2 (0.00%) | 2 / 22 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA BACTERIAL | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 NECROTISING | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POSTOPERATIVE WOUND INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PULMONARY SEPSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 2 / 22 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SEPSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 INFECTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| 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 INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VASCULAR DEVICE INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 | | | |
| HYPERCALCAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOKALAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MALNUTRITION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TYPE 1 DIABETES MELLITUS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| 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** | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 2 (50.00%) | 32 / 47 (68.09%) |
| number of deaths (all causes) | 1 | 1 | 21 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| MALIGNANT NEOPLASM PROGRESSION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TUMOUR HAEMORRHAGE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TUMOUR PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 | | | |
| CAPILLARY LEAK SYNDROME | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEEP VEIN THROMBOSIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EMBOLISM | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VASCULITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| MEDICAL DEVICE REMOVAL | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 | | | |
| CHILLS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FACIAL PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FATIGUE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 2 (50.00%) | 0 / 47 (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 |
| GENERAL PHYSICAL HEALTH DETERIORATION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GENERALISED OEDEMA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 3 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MALAISE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| MEDICAL DEVICE SITE HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OEDEMA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PERFORMANCE STATUS DECREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 4 / 47 (8.51%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 5 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| ANAPHYLACTIC REACTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ANAPHYLACTIC SHOCK | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| SYSTEMIC IMMUNE ACTIVATION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| FEMALE GENITAL TRACT FISTULA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VAGINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| ASPIRATION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ASTHMA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BRONCHOSPASM | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COUGH | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DYSPNOEA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMOPTYSIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LARYNGEAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PHARYNGEAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Product issues | | | |
| DEVICE DISLOCATION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BLOOD BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BLOOD CREATININE INCREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EJECTION FRACTION DECREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HEPATIC ENZYME INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LIVER FUNCTION TEST INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LYMPHOCYTE COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OXYGEN SATURATION DECREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PLATELET COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TRANSAMINASES INCREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 | | | |
| INCORRECT DOSE ADMINISTERED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 | 1 / 3 (33.33%) | 1 / 2 (50.00%) | 7 / 47 (14.89%) |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 1 | 12 / 12 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MEDICATION ERROR | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POST PROCEDURAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 LACERATION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UROSTOMY COMPLICATION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 ACCESS COMPLICATION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders | | | |
| TRACHEO-OESOPHAGEAL FISTULA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYOCARDIAL INFARCTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYOCARDITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PERICARDIAL EFFUSION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 | | | |
| AGNOSIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| APHASIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CEREBRAL ISCHAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CEREBROVASCULAR ACCIDENT | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ENCEPHALOPATHY | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EPILEPSY | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NEURALGIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POLYNEUROPATHY | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 2 (50.00%) | 0 / 47 (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 |
| SYNCOPE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VOCAL CORD PARALYSIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 4 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| 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 UPPER | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COLITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIARRHOEA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTRIC HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| IMMUNE-MEDIATED ENTEROCOLITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LARGE INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MOUTH HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL FISTULA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL STENOSIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PANCREATITIS ACUTE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PROCTALGIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| 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 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SMALL INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| 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 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| BILE DUCT STENOSIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BILIARY OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLECYSTITIS ACUTE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLELITHIASIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DRUG-INDUCED LIVER INJURY | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HEPATITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HEPATOTOXICITY | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 | | | |
| DERMATITIS ACNEIFORM | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PRURITUS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RASH | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| STEVENS-JOHNSON SYNDROME | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| ACUTE KIDNEY INJURY | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMATURIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYDRONEPHROSIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 4 / 47 (8.51%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NEPHRITIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PYELOCALIECTASIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RENAL FAILURE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| 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 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 | | | |
| ADDISON'S DISEASE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| IMMUNE-MEDIATED HYPOPHYSITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 | | | |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYALGIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 2 (50.00%) | 0 / 47 (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 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PATHOLOGICAL FRACTURE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| ABDOMINAL WALL ABSCESS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| APPENDICITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ARTHRITIS BACTERIAL | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ASPERGILLUS INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BACTERIAL INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CORNEAL INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| DEVICE RELATED INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ENCEPHALITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LYMPH GLAND INFECTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PELVIC INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| PERITONEAL ABSCESS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PLEURAL INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 2 (50.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA BACTERIAL | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 NECROTISING | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POSTOPERATIVE WOUND INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PULMONARY SEPSIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SEPSIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SEPTIC SHOCK | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| 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 INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VASCULAR DEVICE INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 | | | |
| HYPERCALCAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| 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 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| 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 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MALNUTRITION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TYPE 1 DIABETES MELLITUS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | ESCC: Part III Cohort I (Q3W) | SCCHN: Part III Cohort G (Q3W) | SCCHN: Part III Cohort H (Q3W) |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 20 / 33 (60.61%) | 15 / 23 (65.22%) | 22 / 30 (73.33%) |
| number of deaths (all causes) | 21 | 14 | 20 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| MALIGNANT NEOPLASM PROGRESSION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TUMOUR HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| TUMOUR PAIN | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| CAPILLARY LEAK SYNDROME | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEEP VEIN THROMBOSIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EMBOLISM | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOTENSION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 2 / 30 (6.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VASCULITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| MEDICAL DEVICE REMOVAL | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| CHILLS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FACIAL PAIN | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (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 |
| FATIGUE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GENERAL PHYSICAL HEALTH DETERIORATION | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (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 |

| | | | |
|---|---|---|---|
| GENERALISED OEDEMA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MALAISE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MEDICAL DEVICE SITE HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OEDEMA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PAIN | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PERFORMANCE STATUS DECREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PYREXIA | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 3 / 30 (10.00%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 4 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| ANAPHYLACTIC REACTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ANAPHYLACTIC SHOCK | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SYSTEMIC IMMUNE ACTIVATION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| FEMALE GENITAL TRACT FISTULA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VAGINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| ASPIRATION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ASTHMA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BRONCHOSPASM | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COUGH | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DYSPNOEA | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 1 / 23 (4.35%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMOPTYSIS | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| LARYNGEAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PHARYNGEAL HAEMORRHAGE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| PNEUMOTHORAX | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PULMONARY EMBOLISM | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RESPIRATORY FAILURE | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| Psychiatric disorders | | | |
| CONFUSIONAL STATE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Product issues | | | |
| DEVICE DISLOCATION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |

| | | | |
|---|---|---|---|
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (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 |
| BLOOD BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BLOOD CREATININE INCREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EJECTION FRACTION DECREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HEPATIC ENZYME INCREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LIVER FUNCTION TEST INCREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LYMPHOCYTE COUNT DECREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OXYGEN SATURATION DECREASED | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (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 |
| PLATELET COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TRANSAMINASES INCREASED | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (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 |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (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 |
| Injury, poisoning and procedural complications | | | |
| INCORRECT DOSE ADMINISTERED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 2 / 23 (8.70%) | 3 / 30 (10.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 2 / 2 | 3 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MEDICATION ERROR | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POST PROCEDURAL HAEMORRHAGE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (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 |
| SKIN LACERATION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UROSTOMY COMPLICATION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VASCULAR ACCESS COMPLICATION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders | | | |
| TRACHEO-OESOPHAGEAL FISTULA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| ATRIAL FIBRILLATION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYOCARDIAL INFARCTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYOCARDITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| PERICARDIAL EFFUSION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (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 |
| Nervous system disorders | | | |
| AGNOSIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| APHASIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CEREBRAL ISCHAEMIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CEREBROVASCULAR ACCIDENT | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (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 |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ENCEPHALOPATHY | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EPILEPSY | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NEURALGIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POLYNEUROPATHY | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VOCAL CORD PARALYSIS | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 2 / 30 (6.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 2 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 3 / 3 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| THROMBOCYTOPENIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COLITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (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 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTRIC HAEMORRHAGE | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| IMMUNE-MEDIATED ENTEROCOLITIS | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (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 |
| INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LARGE INTESTINAL OBSTRUCTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MOUTH HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL FISTULA | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL OBSTRUCTION | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL STENOSIS | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PANCREATITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PANCREATITIS ACUTE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PROCTALGIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RECTAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SMALL INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UPPER GASTROINTESTINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VOMITING | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| BILE DUCT STENOSIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BILIARY OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLECYSTITIS ACUTE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLELITHIASIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DRUG-INDUCED LIVER INJURY | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HEPATITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HEPATOTOXICITY | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| DERMATITIS ACNEIFORM | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PRURITUS | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (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 |
| RASH | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (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 |
| STEVENS-JOHNSON SYNDROME | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |

| | | | |
|---|---|---|---|
| ACUTE KIDNEY INJURY | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 2 / 2 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMATURIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYDRONEPHROSIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NEPHRITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PYELOCALIECTASIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RENAL FAILURE | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| URINARY TRACT OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| ADDISON'S DISEASE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| IMMUNE-MEDIATED HYPOPHYSITIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (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 |
| Musculoskeletal and connective tissue disorders | | | |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYALGIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PATHOLOGICAL FRACTURE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (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 |
| Infections and infestations | | | |
| ABDOMINAL WALL ABSCESS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| APPENDICITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ARTHRITIS BACTERIAL | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (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 |

| | | | |
|---|---|---|---|
| ASPERGILLUS INFECTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BACTERAEMIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BACTERIAL INFECTION | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BRONCHITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (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 |
| CORNEAL INFECTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEVICE RELATED INFECTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ENCEPHALITIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ESCHERICHIA INFECTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFECTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (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 |
| LYMPH GLAND INFECTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PELVIC INFECTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PERITONEAL ABSCESS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PLEURAL INFECTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 2 / 23 (8.70%) | 2 / 30 (6.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| PNEUMONIA BACTERIAL | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA NECROTISING | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POSTOPERATIVE WOUND INFECTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PULMONARY SEPSIS | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SEPSIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SEPTIC SHOCK | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SKIN INFECTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| UPPER RESPIRATORY TRACT INFECTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VASCULAR DEVICE INFECTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| HYPERCALCAEMIA | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 2 / 23 (8.70%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOGLYCAEMIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (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 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPONATRAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 2 / 23 (8.70%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MALNUTRITION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TYPE 1 DIABETES MELLITUS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | ESCC: Part III Cohort M (QW/Q2W) | SCCHN: Part III Cohort K (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 14 / 25 (56.00%) | 1 / 1 (100.00%) |
| number of deaths (all causes) | 2 | 14 | 1 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| MALIGNANT NEOPLASM PROGRESSION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 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 |
| TUMOUR HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 | | | |
| CAPILLARY LEAK SYNDROME | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (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 |
| DEEP VEIN THROMBOSIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| EMBOLISM | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 |
| VASCULITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (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 |
| Surgical and medical procedures | | | |
| MEDICAL DEVICE REMOVAL | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 | | | |
| CHILLS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |

| | | | |
|---|---|---|---|
| FACIAL PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| FATIGUE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 PHYSICAL HEALTH DETERIORATION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| GENERALISED OEDEMA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| MALAISE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| MEDICAL DEVICE SITE HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OEDEMA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| PERFORMANCE STATUS DECREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| ANAPHYLACTIC REACTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| ANAPHYLACTIC SHOCK | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| SYSTEMIC IMMUNE ACTIVATION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| Reproductive system and breast disorders | | | |

| | | | |
|---|---|---|---|
| FEMALE GENITAL TRACT FISTULA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| VAGINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 | | | |
| ASPIRATION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| ASTHMA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| BRONCHOSPASM | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| COUGH | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 |
| HAEMOPTYSIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 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 |

| | | | |
|---|---|---|---|
| LARYNGEAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| PHARYNGEAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| PNEUMONITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 1 / 25 (4.00%) | 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 |
| Product issues | | | |
| DEVICE DISLOCATION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 1 / 1 (100.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 CREATININE INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| EJECTION FRACTION DECREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 ENZYME INCREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| LIVER FUNCTION TEST INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| LYMPHOCYTE COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| OXYGEN SATURATION DECREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| PLATELET COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (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 |
| TRANSAMINASES INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 | | | |

| | | | |
|---|---|---|---|
| INCORRECT DOSE ADMINISTERED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 4 / 25 (16.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 9 / 9 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MEDICATION ERROR | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| POST PROCEDURAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 LACERATION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| UROSTOMY COMPLICATION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 1 / 1 (100.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| VASCULAR ACCESS COMPLICATION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| Congenital, familial and genetic disorders | | | |
| TRACHEO-OESOPHAGEAL FISTULA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 |
| MYOCARDIAL INFARCTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| MYOCARDITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| PERICARDIAL EFFUSION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 | | | |
| AGNOSIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| APHASIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| CEREBRAL ISCHAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |

| | | | |
|---|---|---|---|
| CEREBROVASCULAR ACCIDENT | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| ENCEPHALOPATHY | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| EPILEPSY | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| NEURALGIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| POLYNEUROPATHY | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| VOCAL CORD PARALYSIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 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 |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---|---|---|
| ANAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (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 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 UPPER | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| COLITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (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 |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| GASTRIC HAEMORRHAGE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| IMMUNE-MEDIATED ENTEROCOLITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| LARGE INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| OESOPHAGEAL FISTULA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| OESOPHAGEAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| OESOPHAGEAL STENOSIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 ACUTE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| PROCTALGIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 1 / 25 (4.00%) | 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 |
| SMALL INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 | | | |
| BILE DUCT STENOSIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| BILIARY OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| CHOLECYSTITIS ACUTE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| CHOLELITHIASIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| DRUG-INDUCED LIVER INJURY | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| HEPATITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| HEPATOTOXICITY | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 | | | |
| DERMATITIS ACNEIFORM | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| PRURITUS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| STEVENS-JOHNSON SYNDROME | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 | | | |
| ACUTE KIDNEY INJURY | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 1 / 1 (100.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMATURIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| HYDRONEPHROSIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| NEPHRITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| PYELOCALIECTASIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 FAILURE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (0.00%) | 1 / 1 (100.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| ADDISON'S DISEASE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| IMMUNE-MEDIATED HYPOPHYSITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 | | | |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| MYALGIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 |
| PATHOLOGICAL FRACTURE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 | | | |
| ABDOMINAL WALL ABSCESS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| APPENDICITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| ARTHRITIS BACTERIAL | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| ASPERGILLUS INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 1 / 25 (4.00%) | 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 |
| BACTERIAL INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 |
| CORNEAL INFECTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 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 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| DEVICE RELATED INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 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 |
| ENCEPHALITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| LYMPH GLAND INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| PELVIC INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| PERITONEAL ABSCESS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| PLEURAL INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 4 / 25 (16.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| PNEUMONIA BACTERIAL | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 25 (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 |
| PNEUMONIA NECROTISING | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| POSTOPERATIVE WOUND INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 SEPSIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 DEVICE INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 | | | |
| HYPERCALCAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 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 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| HYPOALBUMINAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 / 2 (0.00%) | 0 / 25 (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 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| MALNUTRITION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |
| TYPE 1 DIABETES MELLITUS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (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 |

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

| **Non-serious adverse events** | NSCLC: Part I Cohort A (QW/Q2W) | NSCLC: Part I Cohort B (QW/Q2W) | NSCLC: Part I Cohort D, Arm 1 (QW/Q2W) |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 25 / 26 (96.15%) | 32 / 32 (100.00%) | 3 / 3 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| TUMOUR PAIN | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vascular disorders | | | |
| CAPILLARY LEAK SYNDROME | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HOT FLUSH | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERTENSION | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| HYPOTENSION | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 11 / 32 (34.38%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 14 | 0 |
| THROMBOSIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 6 / 26 (23.08%) | 7 / 32 (21.88%) | 2 / 3 (66.67%) |
| occurrences (all) | 9 | 8 | 3 |
| CHEST PAIN | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| CHILLS | | | |
| subjects affected / exposed | 12 / 26 (46.15%) | 12 / 32 (37.50%) | 1 / 3 (33.33%) |
| occurrences (all) | 23 | 23 | 1 |
| FATIGUE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 14 / 26 (53.85%) | 15 / 32 (46.88%) | 0 / 3 (0.00%) |
| occurrences (all) | 25 | 21 | 0 |
| HYPERTHERMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| MALAISE | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| MUCOSAL INFLAMMATION | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 1 / 32 (3.13%) | 1 / 3 (33.33%) |
| occurrences (all) | 2 | 1 | 1 |
| OEDEMA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 6 / 26 (23.08%) | 4 / 32 (12.50%) | 1 / 3 (33.33%) |
| occurrences (all) | 6 | 7 | 1 |
| PAIN | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| PYREXIA | | | |
| subjects affected / exposed | 20 / 26 (76.92%) | 29 / 32 (90.63%) | 3 / 3 (100.00%) |
| occurrences (all) | 197 | 91 | 11 |
| XEROSIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Reproductive system and breast disorders | | | |
| VAGINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|---|---|---|---|
| CHRONIC OBSTRUCTIVE PULMONARY DISEASE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COUGH | | | |
| subjects affected / exposed | 4 / 26 (15.38%) | 8 / 32 (25.00%) | 2 / 3 (66.67%) |
| occurrences (all) | 4 | 11 | 2 |
| DYSPHONIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DYSPNOEA | | | |
| subjects affected / exposed | 6 / 26 (23.08%) | 7 / 32 (21.88%) | 1 / 3 (33.33%) |
| occurrences (all) | 8 | 10 | 1 |
| HAEMOPTYSIS | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| NASAL CONGESTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 3 / 32 (9.38%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| PNEUMONITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRODUCTIVE COUGH | | | |
| subjects affected / exposed | 3 / 26 (11.54%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 4 | 2 | 0 |
| RHINORRHOEA | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Psychiatric disorders | | | |
| ANXIETY | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CONFUSIONAL STATE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| INSOMNIA | | | |
| subjects affected / exposed | 4 / 26 (15.38%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 9 / 26 (34.62%) | 9 / 32 (28.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 24 | 12 | 0 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 12 / 26 (46.15%) | 8 / 32 (25.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 27 | 13 | 0 |
| BILIRUBIN CONJUGATED INCREASED | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| BLOOD ALKALINE PHOSPHATASE INCREASED | | | |
| subjects affected / exposed | 4 / 26 (15.38%) | 4 / 32 (12.50%) | 0 / 3 (0.00%) |
| occurrences (all) | 9 | 4 | 0 |
| BLOOD BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 6 / 26 (23.08%) | 6 / 32 (18.75%) | 0 / 3 (0.00%) |
| occurrences (all) | 15 | 11 | 0 |
| BLOOD CHOLESTEROL INCREASED | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| BLOOD CREATININE INCREASED | | | |
| subjects affected / exposed | 3 / 26 (11.54%) | 4 / 32 (12.50%) | 0 / 3 (0.00%) |
| occurrences (all) | 6 | 7 | 0 |
| BLOOD LACTATE DEHYDROGENASE INCREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD URIC ACID INCREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| C-REACTIVE PROTEIN INCREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| EOSINOPHIL COUNT INCREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GAMMA-GLUTAMYLTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 5 / 26 (19.23%) | 4 / 32 (12.50%) | 0 / 3 (0.00%) |
| occurrences (all) | 5 | 9 | 0 |
| HEPATIC ENZYME INCREASED | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| LIPASE INCREASED | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 3 / 32 (9.38%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| LYMPHOCYTE COUNT DECREASED | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 8 | 6 | 0 |
| NEUTROPHIL COUNT DECREASED | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| PLATELET COUNT DECREASED | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| TRANSAMINASES INCREASED | | | |
| subjects affected / exposed | 3 / 26 (11.54%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 6 / 26 (23.08%) | 0 / 32 (0.00%) | 1 / 3 (33.33%) |
| occurrences (all) | 7 | 0 | 1 |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 4 / 26 (15.38%) | 7 / 32 (21.88%) | 0 / 3 (0.00%) |
| occurrences (all) | 11 | 16 | 0 |
| TOOTH FRACTURE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| CARDIAC FAILURE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 4 / 32 (12.50%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| DYSGEUSIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HEADACHE | | | |
| subjects affected / exposed | 4 / 26 (15.38%) | 4 / 32 (12.50%) | 0 / 3 (0.00%) |
| occurrences (all) | 8 | 6 | 0 |
| HYPOAESTHESIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NEUROTOXICITY | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 1 / 3 (33.33%) |
| occurrences (all) | 0 | 0 | 1 |
| PRESYNCOPE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Blood and lymphatic system disorders | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 3 / 26 (11.54%) | 11 / 32 (34.38%) | 0 / 3 (0.00%) |
| occurrences (all) | 3 | 18 | 0 |
| COAGULOPATHY | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LEUKOPENIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LYMPHOCYTOSIS | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 4 / 32 (12.50%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 7 | 0 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 3 / 26 (11.54%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 5 | 2 | 0 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Ear and labyrinth disorders | | | |
| VERTIGO | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gastrointestinal disorders | | | |
| ABDOMINAL DISCOMFORT | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 5 / 26 (19.23%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 5 | 2 | 0 |
| CONSTIPATION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 26 (7.69%) | 3 / 32 (9.38%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 9 / 26 (34.62%) | 9 / 32 (28.13%) | 2 / 3 (66.67%) |
| occurrences (all) | 17 | 10 | 2 |
| DRY MOUTH | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DYSPEPSIA | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTROOESOPHAGEAL REFLUX DISEASE | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| NAUSEA | | | |
| subjects affected / exposed | 11 / 26 (42.31%) | 10 / 32 (31.25%) | 1 / 3 (33.33%) |
| occurrences (all) | 22 | 11 | 2 |
| OESOPHAGEAL PAIN | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| STOMATITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| TOOTHACHE | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VOMITING | | | |
| subjects affected / exposed | 10 / 26 (38.46%) | 7 / 32 (21.88%) | 1 / 3 (33.33%) |
| occurrences (all) | 24 | 10 | 3 |
| Hepatobiliary disorders | | | |
| HEPATOTOXICITY | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERBILIRUBINAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| DERMATITIS | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DERMATITIS ACNEIFORM | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| DRY SKIN | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 4 | 2 | 0 |
| ERYTHEMA | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRURITUS | | | |
| subjects affected / exposed | 6 / 26 (23.08%) | 6 / 32 (18.75%) | 2 / 3 (66.67%) |
| occurrences (all) | 11 | 8 | 2 |
| RASH | | | |
| subjects affected / exposed | 13 / 26 (50.00%) | 5 / 32 (15.63%) | 1 / 3 (33.33%) |
| occurrences (all) | 26 | 5 | 1 |
| RASH MACULAR | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH MACULO-PAPULAR | | | |
| subjects affected / exposed | 3 / 26 (11.54%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| RASH PRURITIC | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| URTICARIA | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Renal and urinary disorders | | | |
| HAEMATURIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PROTEINURIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINARY TRACT OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| GLUCOCORTICOID DEFICIENCY | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERTHYROIDISM | | | |
| subjects affected / exposed | 4 / 26 (15.38%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| HYPOTHYROIDISM | | | |
| subjects affected / exposed | 4 / 26 (15.38%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 4 / 26 (15.38%) | 5 / 32 (15.63%) | 0 / 3 (0.00%) |
| occurrences (all) | 4 | 6 | 0 |
| ARTHRITIS | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| BACK PAIN | | | |
| subjects affected / exposed | 7 / 26 (26.92%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 8 | 4 | 0 |
| BONE PAIN | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| MUSCLE SPASMS | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| MUSCULOSKELETAL PAIN | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| MYALGIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 1 / 3 (33.33%) |
| occurrences (all) | 0 | 3 | 1 |
| NECK PAIN | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Infections and infestations | | | |
| BACTERAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BRONCHITIS | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 1 / 3 (33.33%) |
| occurrences (all) | 0 | 0 | 1 |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NASOPHARYNGITIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 26 (3.85%) | 1 / 32 (3.13%) | 1 / 3 (33.33%) |
| occurrences (all) | 1 | 1 | 1 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 3 / 32 (9.38%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| RHINITIS | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 3 / 26 (11.54%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 7 / 26 (26.92%) | 12 / 32 (37.50%) | 2 / 3 (66.67%) |
| occurrences (all) | 11 | 16 | 3 |
| HYPERCALCAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HYPERGLYCAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| HYPERNATRAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERURICAEMIA | | | |
| subjects affected / exposed | 1 / 26 (3.85%) | 1 / 32 (3.13%) | 0 / 3 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 2 / 26 (7.69%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 4 / 26 (15.38%) | 0 / 32 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 9 | 0 | 0 |
| HYPOMAGNESAEMIA | | | |
| subjects affected / exposed | 3 / 26 (11.54%) | 3 / 32 (9.38%) | 0 / 3 (0.00%) |
| occurrences (all) | 14 | 3 | 0 |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 0 / 26 (0.00%) | 2 / 32 (6.25%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 5 / 26 (19.23%) | 4 / 32 (12.50%) | 0 / 3 (0.00%) |
| occurrences (all) | 12 | 15 | 0 |

| **Non-serious adverse events** | NSCLC: Part I Cohort D, Arm 2 (Q3W) | NSCLC: Part I Cohort D, Arm 3 (Q3W) | NSCLC: Part I Cohort F (Q3W) |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 5 / 5 (100.00%) | 2 / 2 (100.00%) | 21 / 22 (95.45%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| TUMOUR PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| CAPILLARY LEAK SYNDROME | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| HOT FLUSH | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERTENSION | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 0 | 1 |
| HYPOTENSION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 6 / 22 (27.27%) |
| occurrences (all) | 0 | 0 | 6 |
| THROMBOSIS | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| General disorders and administration site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 1 / 2 (50.00%) | 7 / 22 (31.82%) |
| occurrences (all) | 2 | 1 | 8 |
| CHEST PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CHILLS | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 0 / 2 (0.00%) | 9 / 22 (40.91%) |
| occurrences (all) | 4 | 0 | 15 |
| FATIGUE | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 3 / 22 (13.64%) |
| occurrences (all) | 1 | 0 | 6 |
| HYPERTHERMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| MALAISE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUCOSAL INFLAMMATION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 2 (50.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| OEDEMA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 0 | 1 |
| PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PYREXIA | | | |
| subjects affected / exposed | 5 / 5 (100.00%) | 1 / 2 (50.00%) | 15 / 22 (68.18%) |
| occurrences (all) | 11 | 3 | 47 |
| XEROSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| VAGINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| CHRONIC OBSTRUCTIVE PULMONARY DISEASE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COUGH | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 2 (50.00%) | 4 / 22 (18.18%) |
| occurrences (all) | 0 | 1 | 4 |
| DYSPHONIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| DYSPNOEA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 2 (50.00%) | 3 / 22 (13.64%) |
| occurrences (all) | 0 | 1 | 3 |
| HAEMOPTYSIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| NASAL CONGESTION | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PNEUMONITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| PRODUCTIVE COUGH | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| RHINORRHOEA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Psychiatric disorders | | | |
| ANXIETY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CONFUSIONAL STATE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INSOMNIA | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 2 (50.00%) | 3 / 22 (13.64%) |
| occurrences (all) | 1 | 1 | 3 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 3 / 22 (13.64%) |
| occurrences (all) | 1 | 0 | 7 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 5 / 22 (22.73%) |
| occurrences (all) | 1 | 0 | 9 |
| BILIRUBIN CONJUGATED INCREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD ALKALINE PHOSPHATASE INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 2 / 22 (9.09%) |
| occurrences (all) | 0 | 0 | 2 |
| BLOOD BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| BLOOD CHOLESTEROL INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD CREATININE INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD LACTATE DEHYDROGENASE INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD URIC ACID INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| C-REACTIVE PROTEIN INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| EOSINOPHIL COUNT INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GAMMA-GLUTAMYLTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 3 / 22 (13.64%) |
| occurrences (all) | 0 | 0 | 3 |
| HEPATIC ENZYME INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LIPASE INCREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 0 | 1 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LYMPHOCYTE COUNT DECREASED | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| NEUTROPHIL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PLATELET COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| TRANSAMINASES INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 0 / 2 (0.00%) | 2 / 22 (9.09%) |
| occurrences (all) | 2 | 0 | 4 |
| TOOTH FRACTURE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |

| | | | |
|---|---|---|---|
| CARDIAC FAILURE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DYSGEUSIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HEADACHE | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 2 (50.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| HYPOAESTHESIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NEUROTOXICITY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRESYNCOPE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 2 (50.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 1 | 1 |
| Blood and lymphatic system disorders | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 5 / 22 (22.73%) |
| occurrences (all) | 3 | 0 | 7 |
| COAGULOPATHY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LEUKOPENIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| LYMPHOCYTOSIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 2 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 2 / 22 (9.09%) |
| occurrences (all) | 0 | 0 | 3 |
| Ear and labyrinth disorders | | | |
| VERTIGO | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| ABDOMINAL DISCOMFORT | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| CONSTIPATION | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 2 / 22 (9.09%) |
| occurrences (all) | 1 | 0 | 2 |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 3 / 22 (13.64%) |
| occurrences (all) | 0 | 0 | 4 |
| DRY MOUTH | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 2 (50.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DYSPEPSIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTROOESOPHAGEAL REFLUX DISEASE | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 8 / 22 (36.36%) |
| occurrences (all) | 0 | 0 | 11 |
| OESOPHAGEAL PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| STOMATITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| TOOTHACHE | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| VOMITING | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 11 / 22 (50.00%) |
| occurrences (all) | 1 | 0 | 16 |
| Hepatobiliary disorders | | | |
| HEPATOTOXICITY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERBILIRUBINAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| DERMATITIS | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DERMATITIS ACNEIFORM | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DRY SKIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| ERYTHEMA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| PRURITUS | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 0 / 2 (0.00%) | 7 / 22 (31.82%) |
| occurrences (all) | 2 | 0 | 8 |
| RASH | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 3 / 22 (13.64%) |
| occurrences (all) | 1 | 0 | 3 |
| RASH MACULAR | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH MACULO-PAPULAR | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| RASH PRURITIC | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URTICARIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| HAEMATURIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| PROTEINURIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| URINARY TRACT OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| GLUCOCORTICOID DEFICIENCY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERTHYROIDISM | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOTHYROIDISM | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal and connective tissue disorders | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 2 |
| ARTHRITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BACK PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BONE PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUSCLE SPASMS | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 3 / 22 (13.64%) |
| occurrences (all) | 0 | 0 | 3 |
| MUSCULOSKELETAL PAIN | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| MYALGIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 2 (50.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| NECK PAIN | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Infections and infestations | | | |
| BACTERAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BRONCHITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 5 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 0 | 1 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 2 / 22 (9.09%) |
| occurrences (all) | 0 | 0 | 2 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 1 | 0 | 1 |

| | | | |
|---|---|---|---|
| RHINITIS | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 2 (50.00%) | 6 / 22 (27.27%) |
| occurrences (all) | 1 | 1 | 6 |
| HYPERCALCAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERGLYCAEMIA | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| HYPERNATRAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERURICAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 2 / 22 (9.09%) |
| occurrences (all) | 0 | 0 | 4 |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOKALAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 3 / 22 (13.64%) |
| occurrences (all) | 0 | 0 | 3 |
| HYPOMAGNESAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 2 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 2 (0.00%) | 2 / 22 (9.09%) |
| occurrences (all) | 4 | 0 | 3 |

| **Non-serious adverse events** | NSCLC: Part II Cohort E, Arm 1 (QW/Q2W) | NSCLC: Part II Cohort E, Arm 2 (Q3W) | CSCC: Part III Cohort J (Q3W) |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 3 / 3 (100.00%) | 2 / 2 (100.00%) | 47 / 47 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| TUMOUR PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| CAPILLARY LEAK SYNDROME | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HOT FLUSH | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 1 | 0 | 1 |
| HYPERTENSION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 2 (50.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 1 | 2 |
| HYPOTENSION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 6 / 47 (12.77%) |
| occurrences (all) | 0 | 0 | 8 |
| THROMBOSIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| General disorders and administration | | | |

| | | | |
|---|---|---|---|
| site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 23 / 47 (48.94%) |
| occurrences (all) | 2 | 0 | 28 |
| CHEST PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 2 |
| CHILLS | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 12 / 47 (25.53%) |
| occurrences (all) | 3 | 0 | 18 |
| FATIGUE | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 2 (50.00%) | 9 / 47 (19.15%) |
| occurrences (all) | 4 | 1 | 12 |
| HYPERTHERMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 4 / 47 (8.51%) |
| occurrences (all) | 0 | 0 | 23 |
| MALAISE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 2 |
| MUCOSAL INFLAMMATION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 4 / 47 (8.51%) |
| occurrences (all) | 0 | 0 | 5 |
| OEDEMA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 7 / 47 (14.89%) |
| occurrences (all) | 0 | 0 | 9 |
| PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 2 |
| PYREXIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 3 (66.67%) | 1 / 2 (50.00%) | 35 / 47 (74.47%) |
| occurrences (all) | 7 | 3 | 134 |
| XEROSIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| VAGINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 3 / 47 (6.38%) |
| occurrences (all) | 0 | 0 | 4 |
| Respiratory, thoracic and mediastinal disorders | | | |
| CHRONIC OBSTRUCTIVE PULMONARY DISEASE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 7 |
| COUGH | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 6 / 47 (12.77%) |
| occurrences (all) | 1 | 0 | 6 |
| DYSPHONIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 2 |
| DYSPNOEA | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 6 / 47 (12.77%) |
| occurrences (all) | 1 | 0 | 8 |
| HAEMOPTYSIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NASAL CONGESTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 1 | 0 | 1 |
| PNEUMONITIS | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| PRODUCTIVE COUGH | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 1 | 0 | 3 |
| RHINORRHOEA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Psychiatric disorders | | | |
| ANXIETY | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 5 / 47 (10.64%) |
| occurrences (all) | 0 | 0 | 5 |
| CONFUSIONAL STATE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INSOMNIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 8 / 47 (17.02%) |
| occurrences (all) | 0 | 0 | 9 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 2 (50.00%) | 21 / 47 (44.68%) |
| occurrences (all) | 1 | 1 | 49 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 2 (50.00%) | 22 / 47 (46.81%) |
| occurrences (all) | 1 | 1 | 56 |
| BILIRUBIN CONJUGATED INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 3 / 47 (6.38%) |
| occurrences (all) | 0 | 0 | 3 |
| BLOOD ALKALINE PHOSPHATASE INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 11 / 47 (23.40%) |
| occurrences (all) | 0 | 0 | 18 |
| BLOOD BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 3 / 3 (100.00%) | 0 / 2 (0.00%) | 12 / 47 (25.53%) |
| occurrences (all) | 10 | 0 | 14 |
| BLOOD CHOLESTEROL INCREASED | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| BLOOD CREATININE INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 6 / 47 (12.77%) |
| occurrences (all) | 0 | 0 | 7 |
| BLOOD LACTATE DEHYDROGENASE INCREASED | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 6 / 47 (12.77%) |
| occurrences (all) | 3 | 0 | 8 |
| BLOOD URIC ACID INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| C-REACTIVE PROTEIN INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 2 |
| EOSINOPHIL COUNT INCREASED | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| GAMMA-GLUTAMYLTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 16 / 47 (34.04%) |
| occurrences (all) | 4 | 0 | 25 |
| HEPATIC ENZYME INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 4 / 47 (8.51%) |
| occurrences (all) | 0 | 0 | 5 |
| LIPASE INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| LYMPHOCYTE COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 5 / 47 (10.64%) |
| occurrences (all) | 0 | 0 | 9 |
| NEUTROPHIL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 5 |
| PLATELET COUNT DECREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 5 / 47 (10.64%) |
| occurrences (all) | 1 | 0 | 7 |
| TRANSAMINASES INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 3 / 47 (6.38%) |
| occurrences (all) | 0 | 0 | 3 |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 2 |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 2 |
| Injury, poisoning and procedural complications | | | |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 7 / 47 (14.89%) |
| occurrences (all) | 1 | 0 | 16 |
| TOOTH FRACTURE | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cardiac disorders | | | |
| CARDIAC FAILURE | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nervous system disorders | | | |
| DIZZINESS | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 3 / 47 (6.38%) |
| occurrences (all) | 1 | 0 | 5 |
| DYSGEUSIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 2 |
| HEADACHE | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 0 / 2 (0.00%) | 8 / 47 (17.02%) |
| occurrences (all) | 3 | 0 | 9 |
| HYPOAESTHESIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 3 |
| NEUROTOXICITY | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRESYNCOPE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 23 / 47 (48.94%) |
| occurrences (all) | 0 | 0 | 40 |
| COAGULOPATHY | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 3 |
| LEUKOPENIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 3 / 47 (6.38%) |
| occurrences (all) | 0 | 0 | 11 |
| LYMPHOCYTOSIS | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 6 / 47 (12.77%) |
| occurrences (all) | 8 | 0 | 17 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 6 / 47 (12.77%) |
| occurrences (all) | 0 | 0 | 12 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 6 / 47 (12.77%) |
| occurrences (all) | 1 | 0 | 14 |
| Ear and labyrinth disorders | | | |
| VERTIGO | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastrointestinal disorders | | | |
| ABDOMINAL DISCOMFORT | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 10 / 47 (21.28%) |
| occurrences (all) | 0 | 0 | 12 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 2 |
| CONSTIPATION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 6 / 47 (12.77%) |
| occurrences (all) | 0 | 0 | 9 |
| DIARRHOEA | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 17 / 47 (36.17%) |
| occurrences (all) | 2 | 0 | 29 |
| DRY MOUTH | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 4 / 47 (8.51%) |
| occurrences (all) | 0 | 0 | 4 |
| DYSPEPSIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| GASTROOESOPHAGEAL REFLUX DISEASE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| NAUSEA | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 0 / 2 (0.00%) | 19 / 47 (40.43%) |
| occurrences (all) | 2 | 0 | 46 |
| OESOPHAGEAL PAIN | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| STOMATITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 2 |
| TOOTHACHE | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VOMITING | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 18 / 47 (38.30%) |
| occurrences (all) | 0 | 0 | 45 |
| Hepatobiliary disorders | | | |
| HEPATOTOXICITY | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 3 / 47 (6.38%) |
| occurrences (all) | 0 | 0 | 5 |
| HYPERBILIRUBINAEMIA | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 1 | 0 | 8 |
| Skin and subcutaneous tissue disorders | | | |
| DERMATITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 2 |
| DERMATITIS ACNEIFORM | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DRY SKIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 3 / 47 (6.38%) |
| occurrences (all) | 0 | 0 | 3 |
| ERYTHEMA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 3 / 47 (6.38%) |
| occurrences (all) | 0 | 0 | 7 |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 3 / 47 (6.38%) |
| occurrences (all) | 0 | 0 | 3 |
| PRURITUS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 8 / 47 (17.02%) |
| occurrences (all) | 1 | 0 | 9 |
| RASH | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 0 / 2 (0.00%) | 9 / 47 (19.15%) |
| occurrences (all) | 6 | 0 | 15 |
| RASH MACULAR | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH MACULO-PAPULAR | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| RASH PRURITIC | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| URTICARIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 3 / 47 (6.38%) |
| occurrences (all) | 0 | 0 | 3 |
| Renal and urinary disorders | | | |
| HAEMATURIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 4 / 47 (8.51%) |
| occurrences (all) | 0 | 0 | 5 |
| PROTEINURIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 0 | 0 | 2 |
| URINARY TRACT OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| GLUCOCORTICOID DEFICIENCY | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| HYPERTHYROIDISM | | | |
| subjects affected / exposed | 3 / 3 (100.00%) | 0 / 2 (0.00%) | 4 / 47 (8.51%) |
| occurrences (all) | 3 | 0 | 4 |
| HYPOTHYROIDISM | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 3 / 47 (6.38%) |
| occurrences (all) | 1 | 0 | 4 |
| Musculoskeletal and connective tissue disorders | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 2 (50.00%) | 7 / 47 (14.89%) |
| occurrences (all) | 0 | 1 | 9 |
| ARTHRITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BACK PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 9 / 47 (19.15%) |
| occurrences (all) | 0 | 0 | 10 |
| BONE PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 2 (50.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 1 | 1 |
| MUSCLE SPASMS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 1 | 0 | 3 |
| MUSCULOSKELETAL PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MYALGIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| NECK PAIN | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 7 / 47 (14.89%) |
| occurrences (all) | 0 | 0 | 7 |
| Infections and infestations | | | |

| | | | |
|---|---|---|---|
| BACTERAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| BRONCHITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 1 | 0 | 1 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 1 | 0 | 1 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RHINITIS | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 2 (50.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| URINARY TRACT INFECTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 14 / 47 (29.79%) |
| occurrences (all) | 0 | 0 | 19 |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 0 / 2 (0.00%) | 12 / 47 (25.53%) |
| occurrences (all) | 3 | 0 | 15 |
| HYPERCALCAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| HYPERGLYCAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 3 / 47 (6.38%) |
| occurrences (all) | 0 | 0 | 3 |
| HYPERNATRAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERURICAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 1 / 47 (2.13%) |
| occurrences (all) | 0 | 0 | 1 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 6 / 47 (12.77%) |
| occurrences (all) | 0 | 0 | 10 |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 4 / 47 (8.51%) |
| occurrences (all) | 0 | 0 | 6 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 9 / 47 (19.15%) |
| occurrences (all) | 0 | 0 | 11 |
| HYPOMAGNESAEMIA | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 0 / 2 (0.00%) | 8 / 47 (17.02%) |
| occurrences (all) | 3 | 0 | 13 |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 2 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all) | 1 | 0 | 4 |

| | | | |
|---|---|---|---|
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 2 (0.00%) | 9 / 47 (19.15%) |
| occurrences (all) | 0 | 0 | 9 |

| **Non-serious adverse events** | ESCC: Part III Cohort I (Q3W) | SCCHN: Part III Cohort G (Q3W) | SCCHN: Part III Cohort H (Q3W) |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 33 / 33 (100.00%) | 23 / 23 (100.00%) | 29 / 30 (96.67%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| TUMOUR PAIN | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| CAPILLARY LEAK SYNDROME | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| HOT FLUSH | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HYPERTENSION | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 1 / 23 (4.35%) | 1 / 30 (3.33%) |
| occurrences (all) | 2 | 1 | 1 |
| HYPOTENSION | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 4 / 23 (17.39%) | 8 / 30 (26.67%) |
| occurrences (all) | 3 | 5 | 11 |
| THROMBOSIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 8 / 33 (24.24%) | 9 / 23 (39.13%) | 12 / 30 (40.00%) |
| occurrences (all) | 8 | 10 | 12 |
| CHEST PAIN | | | |
| subjects affected / exposed | 3 / 33 (9.09%) | 0 / 23 (0.00%) | 2 / 30 (6.67%) |
| occurrences (all) | 3 | 0 | 2 |
| CHILLS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 12 / 33 (36.36%) | 6 / 23 (26.09%) | 10 / 30 (33.33%) |
| occurrences (all) | 25 | 8 | 10 |
| FATIGUE | | | |
| subjects affected / exposed | 8 / 33 (24.24%) | 6 / 23 (26.09%) | 5 / 30 (16.67%) |
| occurrences (all) | 11 | 9 | 6 |
| HYPERTHERMIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 2 / 30 (6.67%) |
| occurrences (all) | 0 | 0 | 3 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MALAISE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUCOSAL INFLAMMATION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 2 / 30 (6.67%) |
| occurrences (all) | 0 | 3 | 2 |
| OEDEMA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 23 (4.35%) | 2 / 30 (6.67%) |
| occurrences (all) | 2 | 1 | 2 |
| PAIN | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| PYREXIA | | | |
| subjects affected / exposed | 26 / 33 (78.79%) | 18 / 23 (78.26%) | 22 / 30 (73.33%) |
| occurrences (all) | 116 | 76 | 60 |
| XEROSIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| VAGINAL HAEMORRHAGE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| CHRONIC OBSTRUCTIVE PULMONARY DISEASE | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |
| COUGH | | | |
| subjects affected / exposed | 4 / 33 (12.12%) | 2 / 23 (8.70%) | 1 / 30 (3.33%) |
| occurrences (all) | 5 | 2 | 1 |
| DYSPHONIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 3 / 23 (13.04%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| DYSPNOEA | | | |
| subjects affected / exposed | 4 / 33 (12.12%) | 2 / 23 (8.70%) | 3 / 30 (10.00%) |
| occurrences (all) | 5 | 2 | 3 |
| HAEMOPTYSIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 2 / 30 (6.67%) |
| occurrences (all) | 0 | 1 | 4 |
| NASAL CONGESTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| PNEUMONITIS | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| PRODUCTIVE COUGH | | | |
| subjects affected / exposed | 3 / 33 (9.09%) | 1 / 23 (4.35%) | 1 / 30 (3.33%) |
| occurrences (all) | 3 | 1 | 1 |
| RHINORRHOEA | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Psychiatric disorders | | | |

| | | | |
|---|---|---|---|
| ANXIETY | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 1 / 23 (4.35%) | 1 / 30 (3.33%) |
| occurrences (all) | 2 | 1 | 1 |
| CONFUSIONAL STATE | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| INSOMNIA | | | |
| subjects affected / exposed | 3 / 33 (9.09%) | 3 / 23 (13.04%) | 0 / 30 (0.00%) |
| occurrences (all) | 5 | 3 | 0 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 14 / 33 (42.42%) | 12 / 23 (52.17%) | 6 / 30 (20.00%) |
| occurrences (all) | 27 | 21 | 7 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 14 / 33 (42.42%) | 16 / 23 (69.57%) | 6 / 30 (20.00%) |
| occurrences (all) | 25 | 37 | 9 |
| BILIRUBIN CONJUGATED INCREASED | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| BLOOD ALKALINE PHOSPHATASE INCREASED | | | |
| subjects affected / exposed | 5 / 33 (15.15%) | 7 / 23 (30.43%) | 4 / 30 (13.33%) |
| occurrences (all) | 7 | 15 | 5 |
| BLOOD BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 6 / 33 (18.18%) | 5 / 23 (21.74%) | 2 / 30 (6.67%) |
| occurrences (all) | 7 | 10 | 4 |
| BLOOD CHOLESTEROL INCREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD CREATININE INCREASED | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 4 / 23 (17.39%) | 1 / 30 (3.33%) |
| occurrences (all) | 1 | 8 | 3 |
| BLOOD LACTATE DEHYDROGENASE INCREASED | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |

| | | | |
|---|---|---|---|
| BLOOD URIC ACID INCREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 2 / 30 (6.67%) |
| occurrences (all) | 0 | 0 | 3 |
| C-REACTIVE PROTEIN INCREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 0 | 1 |
| EOSINOPHIL COUNT INCREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GAMMA-GLUTAMYLTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 5 / 33 (15.15%) | 12 / 23 (52.17%) | 9 / 30 (30.00%) |
| occurrences (all) | 7 | 28 | 9 |
| HEPATIC ENZYME INCREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 0 | 1 |
| LIPASE INCREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| LYMPHOCYTE COUNT DECREASED | | | |
| subjects affected / exposed | 3 / 33 (9.09%) | 3 / 23 (13.04%) | 0 / 30 (0.00%) |
| occurrences (all) | 9 | 10 | 0 |
| NEUTROPHIL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| PLATELET COUNT DECREASED | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 6 / 23 (26.09%) | 2 / 30 (6.67%) |
| occurrences (all) | 6 | 24 | 2 |
| TRANSAMINASES INCREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 0 | 1 |
| WEIGHT DECREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 33 (6.06%) | 2 / 23 (8.70%) | 3 / 30 (10.00%) |
| occurrences (all) | 2 | 2 | 3 |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 4 / 23 (17.39%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 10 | 0 |
| Injury, poisoning and procedural complications | | | |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 5 / 33 (15.15%) | 2 / 23 (8.70%) | 1 / 30 (3.33%) |
| occurrences (all) | 23 | 13 | 3 |
| TOOTH FRACTURE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| CARDIAC FAILURE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| DIZZINESS | | | |
| subjects affected / exposed | 3 / 33 (9.09%) | 1 / 23 (4.35%) | 2 / 30 (6.67%) |
| occurrences (all) | 3 | 1 | 2 |
| DYSGEUSIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HEADACHE | | | |
| subjects affected / exposed | 7 / 33 (21.21%) | 2 / 23 (8.70%) | 1 / 30 (3.33%) |
| occurrences (all) | 13 | 3 | 1 |
| HYPOAESTHESIA | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 2 / 23 (8.70%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| NEUROTOXICITY | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRESYNCOPE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 3 / 30 (10.00%) |
| occurrences (all) | 1 | 0 | 3 |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 7 / 33 (21.21%) | 15 / 23 (65.22%) | 9 / 30 (30.00%) |
| occurrences (all) | 8 | 29 | 13 |
| COAGULOPATHY | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 2 / 30 (6.67%) |
| occurrences (all) | 0 | 0 | 4 |
| LEUKOPENIA | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| LYMPHOCYTOSIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 3 / 33 (9.09%) | 4 / 23 (17.39%) | 3 / 30 (10.00%) |
| occurrences (all) | 17 | 15 | 7 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 3 / 33 (9.09%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 4 | 0 | 1 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 1 / 23 (4.35%) | 1 / 30 (3.33%) |
| occurrences (all) | 4 | 1 | 1 |
| Ear and labyrinth disorders | | | |
| VERTIGO | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| ABDOMINAL DISCOMFORT | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| ABDOMINAL PAIN | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 33 (6.06%) | 1 / 23 (4.35%) | 1 / 30 (3.33%) |
| occurrences (all) | 2 | 1 | 1 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| CONSTIPATION | | | |
| subjects affected / exposed | 6 / 33 (18.18%) | 5 / 23 (21.74%) | 4 / 30 (13.33%) |
| occurrences (all) | 7 | 6 | 5 |
| DIARRHOEA | | | |
| subjects affected / exposed | 7 / 33 (21.21%) | 3 / 23 (13.04%) | 5 / 30 (16.67%) |
| occurrences (all) | 7 | 3 | 6 |
| DRY MOUTH | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| DYSPEPSIA | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 2 | 12 | 0 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 1 / 23 (4.35%) | 1 / 30 (3.33%) |
| occurrences (all) | 2 | 1 | 1 |
| GASTROOESOPHAGEAL REFLUX DISEASE | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| NAUSEA | | | |
| subjects affected / exposed | 13 / 33 (39.39%) | 6 / 23 (26.09%) | 7 / 30 (23.33%) |
| occurrences (all) | 49 | 14 | 11 |
| OESOPHAGEAL PAIN | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| STOMATITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 2 / 30 (6.67%) |
| occurrences (all) | 0 | 1 | 2 |
| TOOTHACHE | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| VOMITING | | | |
| subjects affected / exposed | 3 / 33 (9.09%) | 5 / 23 (21.74%) | 5 / 30 (16.67%) |
| occurrences (all) | 4 | 19 | 6 |
| Hepatobiliary disorders | | | |
| HEPATOTOXICITY | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERBILIRUBINAEMIA | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 2 / 23 (8.70%) | 0 / 30 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| DERMATITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DERMATITIS ACNEIFORM | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DRY SKIN | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 23 (4.35%) | 1 / 30 (3.33%) |
| occurrences (all) | 1 | 2 | 1 |
| ERYTHEMA | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 1 / 23 (4.35%) | 2 / 30 (6.67%) |
| occurrences (all) | 2 | 1 | 2 |
| PRURITUS | | | |
| subjects affected / exposed | 4 / 33 (12.12%) | 1 / 23 (4.35%) | 2 / 30 (6.67%) |
| occurrences (all) | 7 | 1 | 2 |
| RASH | | | |
| subjects affected / exposed | 4 / 33 (12.12%) | 7 / 23 (30.43%) | 1 / 30 (3.33%) |
| occurrences (all) | 7 | 12 | 1 |
| RASH MACULAR | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 0 | 4 |
| RASH MACULO-PAPULAR | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH PRURITIC | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URTICARIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| HAEMATURIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| PROTEINURIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| URINARY TRACT OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| GLUCOCORTICOID DEFICIENCY | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERTHYROIDISM | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| HYPOTHYROIDISM | | | |
| subjects affected / exposed | 7 / 33 (21.21%) | 4 / 23 (17.39%) | 1 / 30 (3.33%) |
| occurrences (all) | 7 | 4 | 1 |
| Musculoskeletal and connective tissue disorders | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 5 / 33 (15.15%) | 1 / 23 (4.35%) | 2 / 30 (6.67%) |
| occurrences (all) | 6 | 1 | 2 |
| ARTHRITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BACK PAIN | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 33 (9.09%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| BONE PAIN | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUSCLE SPASMS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 0 | 1 |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUSCULOSKELETAL PAIN | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MYALGIA | | | |
| subjects affected / exposed | 4 / 33 (12.12%) | 4 / 23 (17.39%) | 0 / 30 (0.00%) |
| occurrences (all) | 4 | 8 | 0 |
| NECK PAIN | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 2 | 0 | 1 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 2 / 30 (6.67%) |
| occurrences (all) | 1 | 0 | 2 |
| Infections and infestations | | | |
| BACTERAEMIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 2 / 23 (8.70%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| BRONCHITIS | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 2 / 30 (6.67%) |
| occurrences (all) | 0 | 0 | 2 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |

| | | | |
|---|---|---|---|
| GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 3 / 33 (9.09%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 3 | 0 | 1 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 1 / 23 (4.35%) | 1 / 30 (3.33%) |
| occurrences (all) | 3 | 1 | 1 |
| RHINITIS | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 0 / 23 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 0 | 1 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 3 / 23 (13.04%) | 0 / 30 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 4 / 33 (12.12%) | 0 / 23 (0.00%) | 2 / 30 (6.67%) |
| occurrences (all) | 5 | 0 | 2 |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 6 / 33 (18.18%) | 4 / 23 (17.39%) | 11 / 30 (36.67%) |
| occurrences (all) | 8 | 5 | 11 |
| HYPERCALCAEMIA | | | |
| subjects affected / exposed | 3 / 33 (9.09%) | 5 / 23 (21.74%) | 2 / 30 (6.67%) |
| occurrences (all) | 3 | 8 | 4 |
| HYPERGLYCAEMIA | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 23 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| HYPERKALAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HYPERNATRAEMIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 2 / 23 (8.70%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HYPERURICAEMIA | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 3 / 23 (13.04%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 5 / 23 (21.74%) | 2 / 30 (6.67%) |
| occurrences (all) | 5 | 9 | 2 |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 23 (4.35%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 2 / 23 (8.70%) | 3 / 30 (10.00%) |
| occurrences (all) | 2 | 2 | 5 |
| HYPOMAGNESAEMIA | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 4 / 23 (17.39%) | 4 / 30 (13.33%) |
| occurrences (all) | 3 | 5 | 6 |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 8 / 23 (34.78%) | 2 / 30 (6.67%) |
| occurrences (all) | 4 | 13 | 2 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 4 / 33 (12.12%) | 5 / 23 (21.74%) | 5 / 30 (16.67%) |
| occurrences (all) | 13 | 11 | 8 |

| **Non-serious adverse events** | ESCC: Part III Cohort M (QW/Q2W) | SCCHN: Part III Cohort K (QW/Q2W) | CSCC: Part III Cohort N (QW/Q2W) |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 2 / 2 (100.00%) | 24 / 25 (96.00%) | 1 / 1 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| TUMOUR PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Vascular disorders | | | |

| | | | |
|---|---|---|---|
| CAPILLARY LEAK SYNDROME | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HOT FLUSH | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERTENSION | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| HYPOTENSION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 25 (12.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| THROMBOSIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 25 (16.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| CHEST PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| CHILLS | | | |
| subjects affected / exposed | 2 / 2 (100.00%) | 9 / 25 (36.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 7 | 49 | 3 |
| FATIGUE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 11 / 25 (44.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 19 | 1 |
| HYPERTHERMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MALAISE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUCOSAL INFLAMMATION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OEDEMA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| PYREXIA | | | |
| subjects affected / exposed | 2 / 2 (100.00%) | 21 / 25 (84.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 13 | 110 | 4 |
| XEROSIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| VAGINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| CHRONIC OBSTRUCTIVE PULMONARY DISEASE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COUGH | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| DYSPHONIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DYSPNOEA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| HAEMOPTYSIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NASAL CONGESTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| PNEUMONITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| PRODUCTIVE COUGH | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RHINORRHOEA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Psychiatric disorders | | | |
| ANXIETY | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| CONFUSIONAL STATE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| INSOMNIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 9 / 25 (36.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 13 | 0 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 2 (50.00%) | 11 / 25 (44.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 21 | 0 |
| BILIRUBIN CONJUGATED INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD ALKALINE PHOSPHATASE INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 8 / 25 (32.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 15 | 0 |
| BLOOD BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 6 / 25 (24.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 6 | 0 |
| BLOOD CHOLESTEROL INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD CREATININE INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 25 (12.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| BLOOD LACTATE DEHYDROGENASE INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 25 (16.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 6 | 0 |
| BLOOD URIC ACID INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| C-REACTIVE PROTEIN INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| EOSINOPHIL COUNT INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GAMMA-GLUTAMYLTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 12 / 25 (48.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 17 | 0 |
| HEPATIC ENZYME INCREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LIPASE INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| LYMPHOCYTE COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 16 | 0 |
| NEUTROPHIL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PLATELET COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 25 (16.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 8 | 0 |
| TRANSAMINASES INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 25 (12.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 0 | 1 |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 9 | 0 |
| Injury, poisoning and procedural complications | | | |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 5 / 25 (20.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 24 | 0 |
| TOOTH FRACTURE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| CARDIAC FAILURE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DYSGEUSIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HEADACHE | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 4 / 25 (16.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 1 | 10 | 1 |
| HYPOAESTHESIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NEUROTOXICITY | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRESYNCOPE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 11 / 25 (44.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 29 | 0 |
| COAGULOPATHY | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LEUKOPENIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| LYMPHOCYTOSIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 25 (16.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 25 | 0 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 25 (12.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Ear and labyrinth disorders | | | |
| VERTIGO | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| ABDOMINAL DISCOMFORT | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| CONSTIPATION | | | |
| subjects affected / exposed | 2 / 2 (100.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 4 / 25 (16.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 4 | 0 |
| DRY MOUTH | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DYSPEPSIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 25 (12.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTROOESOPHAGEAL REFLUX DISEASE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 11 / 25 (44.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 44 | 1 |
| OESOPHAGEAL PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| STOMATITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| TOOTHACHE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VOMITING | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 1 | 2 |
| Hepatobiliary disorders | | | |
| HEPATOTOXICITY | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERBILIRUBINAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 25 (12.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|---|---|---|
| DERMATITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DERMATITIS ACNEIFORM | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DRY SKIN | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| ERYTHEMA | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 7 | 0 |
| PRURITUS | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 7 / 25 (28.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 9 | 0 |
| RASH | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 4 / 25 (16.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 5 | 0 |
| RASH MACULAR | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| RASH MACULO-PAPULAR | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| RASH PRURITIC | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URTICARIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| HAEMATURIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PROTEINURIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 25 (12.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| URINARY TRACT OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Endocrine disorders | | | |
| GLUCOCORTICOID DEFICIENCY | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERTHYROIDISM | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HYPOTHYROIDISM | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 5 / 25 (20.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 25 (12.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 7 | 0 |
| ARTHRITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| BACK PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 0 | 0 | 1 |
| BONE PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUSCLE SPASMS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| MUSCULOSKELETAL CHEST PAIN | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 2 (50.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| MUSCULOSKELETAL PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MYALGIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| NECK PAIN | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 25 (12.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| BACTERAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BRONCHITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---|---|---|
| PNEUMONIA | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RHINITIS | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 25 (16.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 25 (12.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| HYPERCALCAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| HYPERGLYCAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HYPERNATRAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERURICAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 25 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOALBUMINAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 25 (4.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HYPOMAGNESAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 25 (8.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 25 (16.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 7 | 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 5 / 25 (20.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 7 | 0 |

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 09 May 2018 | 1. Part I Cohort D was added to enroll platinum treatment experienced, CPI treatment experienced, docetaxel treatment experienced stage IV NSCLC participants. Cohort D comprised 3 arms. Arm 1 and Arm 2 explored different treatment schedules for RO6874281 in combination with atezolizumab. Participants in Arm 3 received gemcitabine or vinorelbine treatment and served as control.<br>2. Part II Cohort E was added to enroll treatment naïve stage IV NSCLC participants that express high levels of PD-L1.<br>Cohort E comprises 2 arms. Arm 1 and Arm 2 explored different treatment schedules for RO6874281 in combination with atezolizumab. |
| 23 August 2018 | 1. An additional cohort, Cohort F, was added to Part I of this study. Forty response-evaluable participants were planned for this cohort in order to gain a better understanding of the safety and tolerability of the combination of RO6874281 and atezolizumab on an Q3W schedule in a specific NSCLC.<br>2. An additional part, Part III, was added to the study design. Part III was dedicated to the exploration of RO6874281 in combination with atezolizumab in metastatic or locally advanced solid cancers with squamous histology. Part III comprised Cohorts G, H, I, and J.<br>3. Implementation of a 10-mg flat dose based upon a simulation using the population pharmacokinetic model that showed overlapping exposures to the dosing regimens of 10 mg followed by 15 mg. |
| 29 March 2019 | 1. An additional four cohorts (ie, Cohorts K, L, M, and N) were added to Part III of this study.<br>2. The sample size of Cohorts D and E were changed due to early termination of these cohorts.<br>3. Inclusion criteria were updated to align criteria across studies in the clinical development program and to clarify that the biopsy requirements enabling enrollment of participants with head and neck cancer presenting with one lesion does not apply to participants in Cohorts G, H, K, and L.<br>4. The evaluation of preliminary activity based on immune-modified (im) RECIST was omitted.<br>5. A general exclusion criterion (ie, exclusion #21) was added to indicate that a 28-day wash-out period from previous cytostatic treatment was required.<br>6. Safety information pertaining to the risk associated with atezolizumab was updated by adding myositis as a new identified risk.<br>7. The defined treatment lengths was updated. |
| 08 April 2019 | The additional four cohorts (i.e., Cohorts K, M, and N and Cohort L) were added to the exclusion criteria. |
| 16 December 2019 | Assessment of echocardiography was removed from the 28-day follow-up visit as the period between discontinuation and follow-up was not long enough to expect any clinically relevant changes in the outcome of repeated testing.<br>2. Benefit risk was updated with new safety information. The enrollment into this study was suspended for participants that were naïve to checkpoint inhibitor treatment (CPI-naïve participants) that otherwise were eligible for CIT/CPI treatment as part of their 1L or 2L standard of care treatment for metastatic disease.<br>3. Dose for QW/Q2W RO6874281 were added for Part III. |
| 25 June 2020 | The main purpose of this amendment was to lift the temporary recruitment suspension for CPI-naïve participants that otherwise were eligible for CPI treatment as part of their 1L or 2L standard of care treatment and to resume enrollment for all CPI-naïve participants in study BP40234. |

| | |
|---|---|
| 21 December 2020 | 1. Severe cutaneous adverse reactions was added as a risk associated with atezolizumab.<br>2. Events suggestive of hemophagocytic lymphohistiocytosis or macrophage activation syndrome was added to the list of non-serious adverse events of special interest.<br>3. RO6874281 was replaced by simlukafusp alfa, the international nonproprietary name, throughout the protocol.<br>4. PD Sample (fluorescence-activated cell sorting [FACS]) Basic, PD Sample (Plasma), PD Sample (Serum) at 24, 36, 48, 60, 72, 84, and 96 weeks after Cycle 1 Day 1 and PD Sample (FACS) Advanced at 24, 48, and 96 weeks after Cycle 1 Day 1 were no longer collected in all cohorts irrespective of the treatment regimens, i.e., Q3W and QW/Q2W.<br>5. During the further conduct of the study, the collection of the on-treatment biopsy scheduled on Cycle 2 Day 8 and Cycle 3 Day 8 for the Q3W and the QW/Q2W schedule, respectively, were regarded as optional for participants enrolled in Part III.<br>5. A treatment cap of 24 months was added. However, in case the participant had reached the defined duration and continues to derive benefit, a longer treatment duration might be granted by the Sponsor. |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported