



Clinical trial results:

A Phase 3, Randomized, Double-Blind Study of Pamrevlumab or Placebo in combination with Gemcitabine Plus Nab-paclitaxel or FOLFIRINOX as Neoadjuvant Treatment in Patients with Locally Advanced, Unresectable Pancreatic Cancer

Summary

| | |
|--------------------------|----------------------|
| EudraCT number | 2019-001925-28 |
| Trial protocol | AT ES DE GB FR BE IT |
| Global end of trial date | 11 June 2024 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 31 October 2024 |
| First version publication date | 31 October 2024 |

Trial information

Trial identification

| | |
|-----------------------|---------------|
| Sponsor protocol code | FGCL-3019-087 |
|-----------------------|---------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03941093 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | FibroGen, Inc. |
| Sponsor organisation address | 409 Illinois Street, San Francisco, United States, CA 94158 |
| Public contact | Clinical Trial Information Desk, FibroGen, Inc., lapis@fibrogen.com |
| Scientific contact | Clinical Trial Information Desk, FibroGen, Inc., lapis@fibrogen.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 | 19 July 2024 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 11 June 2024 |
| Global end of trial reached? | Yes |
| Global end of trial date | 11 June 2024 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this trial is to evaluate the efficacy and safety of neoadjuvant treatment with pamrevlumab in combination with either gemcitabine plus nab-paclitaxel or FOLFIRINOX when compared to treatment with placebo in combination with either gemcitabine plus nab-paclitaxel or FOLFIRINOX in locally advanced, unresectable pancreatic cancer.

Protection of trial subjects:

This trial was conducted according to the International Conference On Harmonization (ICH) Harmonized Tripartite Guideline in compliance with Good Clinical Practices (GCP), including the archiving of essential documents.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------|
| Actual start date of recruitment | 10 May 2019 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--|
| Country: Number of subjects enrolled | United States: 99 |
| Country: Number of subjects enrolled | Canada: 17 |
| Country: Number of subjects enrolled | France: 27 |
| Country: Number of subjects enrolled | Italy: 24 |
| Country: Number of subjects enrolled | Spain: 27 |
| Country: Number of subjects enrolled | Belgium: 8 |
| Country: Number of subjects enrolled | Israel: 4 |
| Country: Number of subjects enrolled | Germany: 10 |
| Country: Number of subjects enrolled | Austria: 4 |
| Country: Number of subjects enrolled | United Kingdom: 11 |
| Country: Number of subjects enrolled | Korea, Democratic People's Republic of: 32 |
| Country: Number of subjects enrolled | China: 21 |
| Worldwide total number of subjects | 284 |
| EEA total number of subjects | 100 |

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) | 140 |
| From 65 to 84 years | 143 |
| 85 years and over | 1 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were randomized in a 1:1 ratio to one of the 2 study treatment arms: Pamrevlumab with Gemcitabine/Nab-paclitaxel or FOLFIRINOX or Placebo with Gemcitabine/Nab-paclitaxel or FOLFIRINOX.

Period 1

| | |
|------------------------------|--|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Carer, Assessor |

Arms

| | |
|------------------------------|--|
| Are arms mutually exclusive? | Yes |
| Arm title | Pamrevlumab + Gemcitabine/Nab-paclitaxel or FOLFIRINOX |

Arm description:

Participants received pamrevlumab in combination with one chemotherapy treatment regimen (gemcitabine plus nab-paclitaxel or FOLFIRINOX) over a 28-day cycle, for up to 6 cycles. Pamrevlumab was administered on Days 1, 8 and 15 of Treatment Cycle 1 and on Day 1 and 15 of each subsequent treatment cycle via intravenous (IV) infusion. Nab-paclitaxel was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. Gemcitabine was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. FOLFIRINOX was a combination of several agents administered on Days 1 and 15 of each 28-day treatment cycle via IV infusion. The specific agents were oxaliplatin, folinic acid, irinotecan, and fluorouracil.

| | |
|--|-----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Pamrevlumab |
| Investigational medicinal product code | FG-3019 |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Pamrevlumab was administered per schedule specified in the arm description.

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

Dosage and administration details:

FOLFIRINOX is a combination of several agents including Oxaliplatin, Folinic Acid, Irinotecan, and Fluorouracil. FOLFIRINOX was administered per schedule specified in the arm description.

| | |
|--|---------------------------------|
| Investigational medicinal product name | Gemcitabine plus Nab-paclitaxel |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Gemcitabine plus nab-paclitaxel was administered per schedule specified in the arm description.

| | |
|------------------|--|
| Arm title | Placebo + Gemcitabine/Nab-paclitaxel or FOLFIRINOX |
|------------------|--|

Arm description:

Participants received pamrevlumab matched placebo in combination with one chemotherapy treatment regimen (gemcitabine plus nab-paclitaxel or FOLFIRINOX) over a 28-day cycle, for up to 6 cycles. Placebo was administered on Days 1, 8 and 15 of Treatment Cycle 1 and on Day 1 and 15 of each subsequent treatment cycle via IV infusion. Nab-paclitaxel was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. Gemcitabine was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. FOLFIRINOX was a combination of several agents administered on Days 1 and 15 of each 28-day treatment cycle via IV infusion. The specific agents were oxaliplatin, folinic acid, irinotecan, and fluorouracil.

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

Dosage and administration details:

Placebo matched to pamrevlumab was administered per schedule specified in the arm description.

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

Dosage and administration details:

FOLFIRINOX is a combination of several agents including Oxaliplatin, Folinic Acid, Irinotecan, and Fluorouracil. FOLFIRINOX was administered per schedule specified in the arm description.

| | |
|--|---------------------------------|
| Investigational medicinal product name | Gemcitabine plus Nab-paclitaxel |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Gemcitabine plus nab-paclitaxel was administered per schedule specified in the arm description.

| Number of subjects in period 1 | Pamrevlumab + Gemcitabine/Nab- paclitaxel or FOLFIRINOX | Placebo + Gemcitabine/Nab- paclitaxel or FOLFIRINOX |
|--|--|--|
| Started | 143 | 141 |
| Received At Least 1 Dose of Study Drug | 142 | 141 |
| Completed | 134 | 134 |
| Not completed | 9 | 7 |
| Consent withdrawn by subject | 9 | 6 |
| Protocol deviation | - | 1 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Pamrevlumab + Gemcitabine/Nab-paclitaxel or FOLFIRINOX |
|-----------------------|--|

Reporting group description:

Participants received pamrevlumab in combination with one chemotherapy treatment regimen (gemcitabine plus nab-paclitaxel or FOLFIRINOX) over a 28-day cycle, for up to 6 cycles. Pamrevlumab was administered on Days 1, 8 and 15 of Treatment Cycle 1 and on Day 1 and 15 of each subsequent treatment cycle via intravenous (IV) infusion. Nab-paclitaxel was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. Gemcitabine was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. FOLFIRINOX was a combination of several agents administered on Days 1 and 15 of each 28-day treatment cycle via IV infusion. The specific agents were oxaliplatin, folinic acid, irinotecan, and fluorouracil.

| | |
|-----------------------|--|
| Reporting group title | Placebo + Gemcitabine/Nab-paclitaxel or FOLFIRINOX |
|-----------------------|--|

Reporting group description:

Participants received pamrevlumab matched placebo in combination with one chemotherapy treatment regimen (gemcitabine plus nab-paclitaxel or FOLFIRINOX) over a 28-day cycle, for up to 6 cycles. Placebo was administered on Days 1, 8 and 15 of Treatment Cycle 1 and on Day 1 and 15 of each subsequent treatment cycle via IV infusion. Nab-paclitaxel was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. Gemcitabine was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. FOLFIRINOX was a combination of several agents administered on Days 1 and 15 of each 28-day treatment cycle via IV infusion. The specific agents were oxaliplatin, folinic acid, irinotecan, and fluorouracil.

| Reporting group values | Pamrevlumab + Gemcitabine/Nab-paclitaxel or FOLFIRINOX | Placebo + Gemcitabine/Nab-paclitaxel or FOLFIRINOX | Total |
|------------------------------------|--|--|-------|
| Number of subjects | 143 | 141 | 284 |
| Age categorical Units: Subjects | | | |

| | | | |
|---|--------|--------|-----|
| Age Continuous Units: years | | | |
| arithmetic mean | 64.5 | 64.5 | |
| standard deviation | ± 9.54 | ± 9.60 | - |
| Sex: Female, Male Units: participants | | | |
| Female | 61 | 72 | 133 |
| Male | 82 | 69 | 151 |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 2 | 2 |
| Asian | 25 | 35 | 60 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 5 | 5 | 10 |
| White | 96 | 79 | 175 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 17 | 20 | 37 |
| Ethnicity (NIH/OMB) Units: Subjects | | | |
| Hispanic or Latino | 10 | 2 | 12 |
| Not Hispanic or Latino | 122 | 124 | 246 |

| | | | |
|-------------------------|----|----|----|
| Unknown or Not Reported | 11 | 15 | 26 |
|-------------------------|----|----|----|

End points

End points reporting groups

| | |
|---|--|
| Reporting group title | Pamrevlumab + Gemcitabine/Nab-paclitaxel or FOLFIRINOX |
| Reporting group description: | |
| Participants received pamrevlumab in combination with one chemotherapy treatment regimen (gemcitabine plus nab-paclitaxel or FOLFIRINOX) over a 28-day cycle, for up to 6 cycles. Pamrevlumab was administered on Days 1, 8 and 15 of Treatment Cycle 1 and on Day 1 and 15 of each subsequent treatment cycle via intravenous (IV) infusion. Nab-paclitaxel was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. Gemcitabine was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. FOLFIRINOX was a combination of several agents administered on Days 1 and 15 of each 28-day treatment cycle via IV infusion. The specific agents were oxaliplatin, folinic acid, irinotecan, and fluorouracil. | |
| Reporting group title | Placebo + Gemcitabine/Nab-paclitaxel or FOLFIRINOX |
| Reporting group description: | |
| Participants received pamrevlumab matched placebo in combination with one chemotherapy treatment regimen (gemcitabine plus nab-paclitaxel or FOLFIRINOX) over a 28-day cycle, for up to 6 cycles. Placebo was administered on Days 1, 8 and 15 of Treatment Cycle 1 and on Day 1 and 15 of each subsequent treatment cycle via IV infusion. Nab-paclitaxel was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. Gemcitabine was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. FOLFIRINOX was a combination of several agents administered on Days 1 and 15 of each 28-day treatment cycle via IV infusion. The specific agents were oxaliplatin, folinic acid, irinotecan, and fluorouracil. | |

Primary: Overall Survival

| | |
|--|------------------|
| End point title | Overall Survival |
| End point description: | |
| Overall survival was defined as the time from date of randomization to date of death due to any cause. Overall survival was calculated using the Kaplan-Meier method. The intent-to-treat (ITT) population included all randomized participants regardless of whether or not study treatment was received. | |
| End point type | Primary |
| End point timeframe: | |
| Up to approximately 5 years | |

| End point values | Pamrevlumab + Gemcitabine/Nab-paclitaxel or FOLFIRINOX | Placebo + Gemcitabine/Nab-paclitaxel or FOLFIRINOX | | |
|----------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 143 | 141 | | |
| Units: months | | | | |
| median (confidence interval 95%) | 17.25 (15.47 to 18.89) | 17.94 (14.59 to 20.34) | | |

Statistical analyses

| | |
|----------------------------|--|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Pamrevlumab + Gemcitabine/Nab-paclitaxel or FOLFIRINOX v |

| | |
|---|--|
| | Placebo + Gemcitabine/Nab-paclitaxel or FOLFIRINOX |
| Number of subjects included in analysis | 284 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.5487 |
| Method | Stratified Log Rank Test |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.08 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.83 |
| upper limit | 1.41 |

Secondary: Progression-free Survival (PFS) as Assessed Using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1

| | |
|-----------------|--|
| End point title | Progression-free Survival (PFS) as Assessed Using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 |
|-----------------|--|

End point description:

The PFS was defined as time from date of randomization until disease progression or death due to any cause, whichever occurred first. PFS was calculated using the Kaplan-Meier method. Progression was defined as at least a 20% increase in the sum of the diameters of target lesions, taking as reference the smallest sum on study. In addition to the relative increase of 20%, the sum must also have demonstrated an absolute increase of at least 5 millimeters (mm). Unequivocal progression of existing non-target lesions and the appearance of one or more new lesions was also considered progression. The ITT population included all randomized participants regardless of whether or not study treatment was received.

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

End point timeframe:

Up to approximately 5 years

| End point values | Pamrevlumab + Gemcitabine/Nab-paclitaxel or FOLFIRINOX | Placebo + Gemcitabine/Nab-paclitaxel or FOLFIRINOX | | |
|----------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 143 | 141 | | |
| Units: months | | | | |
| median (confidence interval 95%) | 9.36 (7.75 to 11.79) | 9.40 (7.69 to 10.84) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Best Overall Objective Response as Assessed Using RECIST v1.1

| | |
|--|---|
| End point title | Number of Participants With Best Overall Objective Response as Assessed Using RECIST v1.1 |
| End point description: Best overall objective response was defined as a complete response (CR) or partial response (PR). CR was defined as disappearance of all target or non-target lesions and normalization of tumor marker level (for non-target lesions), any pathological lymph nodes (whether target or non-target) must have reduced in short axis to <10 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 ITT population included all randomized participants regardless of whether or not study treatment was received. | |
| End point type | Secondary |
| End point timeframe: Up to approximately 5 years | |

| End point values | Pamrevlumab + Gemcitabine/Nab-paclitaxel or FOLFIRINOX | Placebo + Gemcitabine/Nab-paclitaxel or FOLFIRINOX | | |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 143 | 141 | | |
| Units: participants | 43 | 64 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Event-free Survival (EFS)

| | |
|---|---------------------------|
| End point title | Event-free Survival (EFS) |
| End point description: The EFS endpoint was a composite time-to-event endpoint. The event being analyzed ('treatment failure') was defined as the earliest occurrence of: a) failure to achieve disease-free status locally after completion of neoadjuvant treatment and/or after surgery (that is, resection failure or progression that precludes surgery); b) local or distant recurrence, or c) death. The EFS was calculated using the Kaplan-Meier method. The ITT population included all randomized participants regardless of whether or not study treatment was received. | |
| End point type | Secondary |
| End point timeframe: Up to approximately 5 years | |

| End point values | Pamrevlumab + Gemcitabine/Nab-paclitaxel or FOLFIRINOX | Placebo + Gemcitabine/Nab-paclitaxel or FOLFIRINOX | | |
|----------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 143 | 141 | | |
| Units: months | | | | |
| median (confidence interval 95%) | 5.72 (5.59 to 6.01) | 5.78 (5.62 to 6.37) | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 5 years

Adverse event reporting additional description:

Per planned analysis all-cause mortality data were collected and reported for all randomized participants. Adverse events (serious and other) were collected and reported for all randomized participants who received study drug.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 26.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Placebo + Gemcitabine/Nab-paclitaxel or FOLFIRINOX |
|-----------------------|--|

Reporting group description:

Participants received pamrevlumab matched placebo in combination with one chemotherapy treatment regimen (gemcitabine plus nab-paclitaxel or FOLFIRINOX) over a 28-day cycle, for up to 6 cycles. Placebo was administered on Days 1, 8 and 15 of Treatment Cycle 1 and on Day 1 and 15 of each subsequent treatment cycle via IV infusion. Nab-paclitaxel was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. Gemcitabine was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. FOLFIRINOX was a combination of several agents administered on Days 1 and 15 of each 28-day treatment cycle via IV infusion. The specific agents were oxaliplatin, folinic acid, irinotecan, and fluorouracil.

| | |
|-----------------------|--|
| Reporting group title | Pamrevlumab + Gemcitabine/Nab-paclitaxel or FOLFIRINOX |
|-----------------------|--|

Reporting group description:

Participants received pamrevlumab in combination with one chemotherapy treatment regimen (gemcitabine plus nab-paclitaxel or FOLFIRINOX) over a 28-day cycle, for up to 6 cycles. Pamrevlumab was administered on Days 1, 8 and 15 of Treatment Cycle 1 and on Day 1 and 15 of each subsequent treatment cycle via IV infusion. Nab-paclitaxel was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. Gemcitabine was administered on Days 1, 8 and 15 of each 28-day treatment cycle via IV infusion. FOLFIRINOX was a combination of several agents administered on Days 1 and 15 of each 28-day treatment cycle via IV infusion. The specific agents were oxaliplatin, folinic acid, irinotecan, and fluorouracil.

| Serious adverse events | Placebo + Gemcitabine/Nab-paclitaxel or FOLFIRINOX | Pamrevlumab + Gemcitabine/Nab-paclitaxel or FOLFIRINOX | |
|---|--|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 62 / 141 (43.97%) | 75 / 142 (52.82%) | |
| number of deaths (all causes) | 112 | 118 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Malignant neoplasm progression | | | |
| subjects affected / exposed | 2 / 141 (1.42%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cancer pain | | | |

| | | | |
|--|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 141 (0.00%) | 2 / 142 (1.41%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 2 / 141 (1.42%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 2 / 141 (1.42%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypothermia | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Death | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 3 / 142 (2.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 6 / 141 (4.26%) | 5 / 142 (3.52%) | |
| occurrences causally related to treatment / all | 2 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pneumonitis | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 3 / 142 (2.11%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 2 / 142 (1.41%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Pulmonary oedema | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 2 / 141 (1.42%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung disorder | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Anxiety disorder | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Product issues | | | |
| Device occlusion | | | |
| subjects affected / exposed | 2 / 141 (1.42%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Investigations | | | |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 2 / 141 (1.42%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Platelet count decreased | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural fistula | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural fever | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Anastomotic complication | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint dislocation | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip fracture | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal compression fracture | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Hydrocele | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac arrest | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Cardiac failure | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Syncope | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalopathy | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic stroke | | | |
| subjects affected / exposed | 2 / 141 (1.42%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Haemolytic uraemic syndrome | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 2 / 141 (1.42%) | 4 / 142 (2.82%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 2 / 142 (1.41%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Colitis | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 4 / 142 (2.82%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 3 / 141 (2.13%) | 4 / 142 (2.82%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal ischaemia | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jejunal perforation | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstruction gastric | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varices oesophageal | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorder | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocolitis | | | |
| subjects affected / exposed | 2 / 141 (1.42%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal obstruction | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ascites | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal adhesions | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |
| subjects affected / exposed | 4 / 141 (2.84%) | 2 / 142 (1.41%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 6 / 141 (4.26%) | 3 / 142 (2.11%) | |
| occurrences causally related to treatment / all | 2 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 3 / 141 (2.13%) | 4 / 142 (2.82%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 2 / 142 (1.41%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal distension | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematemesis | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 2 / 141 (1.42%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic fistula | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaundice cholestatic | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 2 / 142 (1.41%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder rupture | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 2 / 142 (1.41%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 141 (0.00%) | 2 / 142 (1.41%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary obstruction | | | |
| subjects affected / exposed | 5 / 141 (3.55%) | 3 / 142 (2.11%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis | | | |
| subjects affected / exposed | 8 / 141 (5.67%) | 7 / 142 (4.93%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver injury | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cytolysis | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis acute | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant biliary obstruction | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Erythema | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pseudocellulitis | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Urinary retention | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal injury | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute kidney injury | | | |
| subjects affected / exposed | 2 / 141 (1.42%) | 4 / 142 (2.82%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|-----------------|-----------------|--|
| Spinal osteoarthritis | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Enterocolitis infectious | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis infective | | | |
| subjects affected / exposed | 3 / 141 (2.13%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis infective | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Catheter site infection | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary tract infection | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumocystis jirovecii pneumonia | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 2 / 142 (1.41%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver abscess | | | |
| subjects affected / exposed | 3 / 141 (2.13%) | 2 / 142 (1.41%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 4 / 141 (2.84%) | 5 / 142 (3.52%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 7 / 142 (4.93%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia sepsis | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenic sepsis | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural infection | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic shock | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tongue fungal infection | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COVID-19 | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related infection | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal sepsis | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal bacteraemia | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Hypophosphataemia | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 141 (0.00%) | 3 / 142 (2.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 2 / 142 (1.41%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decreased appetite | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 141 (0.00%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malnutrition | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 1 / 142 (0.70%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperlipidaemia | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 2 / 141 (1.42%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 1 / 141 (0.71%) | 0 / 142 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Placebo + Gemcitabine/Nab- paclitaxel or FOLFIRINOX | Pamrevlumab + Gemcitabine/Nab- paclitaxel or FOLFIRINOX | |
|---|--|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 140 / 141 (99.29%) | 139 / 142 (97.89%) | |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 13 / 141 (9.22%) | 16 / 142 (11.27%) | |
| occurrences (all) | 15 | 17 | |
| Hypertension | | | |
| subjects affected / exposed | 8 / 141 (5.67%) | 5 / 142 (3.52%) | |
| occurrences (all) | 8 | 12 | |
| General disorders and administration site conditions | | | |

| | | | |
|---|-------------------|-------------------|--|
| Fatigue | | | |
| subjects affected / exposed | 76 / 141 (53.90%) | 84 / 142 (59.15%) | |
| occurrences (all) | 164 | 178 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 52 / 141 (36.88%) | 44 / 142 (30.99%) | |
| occurrences (all) | 75 | 59 | |
| Asthenia | | | |
| subjects affected / exposed | 27 / 141 (19.15%) | 27 / 142 (19.01%) | |
| occurrences (all) | 45 | 68 | |
| Pyrexia | | | |
| subjects affected / exposed | 30 / 141 (21.28%) | 30 / 142 (21.13%) | |
| occurrences (all) | 64 | 60 | |
| Chills | | | |
| subjects affected / exposed | 11 / 141 (7.80%) | 10 / 142 (7.04%) | |
| occurrences (all) | 17 | 15 | |
| Influenza like illness | | | |
| subjects affected / exposed | 8 / 141 (5.67%) | 4 / 142 (2.82%) | |
| occurrences (all) | 19 | 5 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Dyspnoea | | | |
| subjects affected / exposed | 18 / 141 (12.77%) | 17 / 142 (11.97%) | |
| occurrences (all) | 31 | 28 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 5 / 141 (3.55%) | 8 / 142 (5.63%) | |
| occurrences (all) | 5 | 8 | |
| Epistaxis | | | |
| subjects affected / exposed | 14 / 141 (9.93%) | 12 / 142 (8.45%) | |
| occurrences (all) | 18 | 19 | |
| Cough | | | |
| subjects affected / exposed | 21 / 141 (14.89%) | 10 / 142 (7.04%) | |
| occurrences (all) | 25 | 12 | |
| Psychiatric disorders | | | |
| Insomnia | | | |
| subjects affected / exposed | 20 / 141 (14.18%) | 16 / 142 (11.27%) | |
| occurrences (all) | 25 | 16 | |
| Anxiety | | | |

| | | | |
|--|-------------------|-------------------|--|
| subjects affected / exposed | 10 / 141 (7.09%) | 6 / 142 (4.23%) | |
| occurrences (all) | 11 | 6 | |
| Depression | | | |
| subjects affected / exposed | 8 / 141 (5.67%) | 4 / 142 (2.82%) | |
| occurrences (all) | 10 | 5 | |
| Investigations | | | |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 56 / 141 (39.72%) | 51 / 142 (35.92%) | |
| occurrences (all) | 170 | 128 | |
| White blood cell count decreased | | | |
| subjects affected / exposed | 28 / 141 (19.86%) | 24 / 142 (16.90%) | |
| occurrences (all) | 130 | 64 | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 19 / 141 (13.48%) | 19 / 142 (13.38%) | |
| occurrences (all) | 25 | 31 | |
| Weight decreased | | | |
| subjects affected / exposed | 18 / 141 (12.77%) | 19 / 142 (13.38%) | |
| occurrences (all) | 26 | 29 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 12 / 141 (8.51%) | 17 / 142 (11.97%) | |
| occurrences (all) | 24 | 29 | |
| Platelet count decreased | | | |
| subjects affected / exposed | 43 / 141 (30.50%) | 36 / 142 (25.35%) | |
| occurrences (all) | 131 | 125 | |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 9 / 141 (6.38%) | 8 / 142 (5.63%) | |
| occurrences (all) | 15 | 18 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 4 / 141 (2.84%) | 9 / 142 (6.34%) | |
| occurrences (all) | 5 | 14 | |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 18 / 141 (12.77%) | 5 / 142 (3.52%) | |
| occurrences (all) | 106 | 23 | |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|--------------------------|--------------------------|--|
| Fall subjects affected / exposed occurrences (all) | 7 / 141 (4.96%) 9 | 10 / 142 (7.04%) 13 | |
| Nervous system disorders | | | |
| Dysgeusia subjects affected / exposed occurrences (all) | 26 / 141 (18.44%) 34 | 23 / 142 (16.20%) 30 | |
| Peripheral sensory neuropathy subjects affected / exposed occurrences (all) | 29 / 141 (20.57%) 53 | 23 / 142 (16.20%) 31 | |
| Paraesthesia subjects affected / exposed occurrences (all) | 18 / 141 (12.77%) 30 | 17 / 142 (11.97%) 38 | |
| Neuropathy peripheral subjects affected / exposed occurrences (all) | 26 / 141 (18.44%) 41 | 30 / 142 (21.13%) 59 | |
| Headache subjects affected / exposed occurrences (all) | 18 / 141 (12.77%) 29 | 15 / 142 (10.56%) 22 | |
| Dizziness subjects affected / exposed occurrences (all) | 22 / 141 (15.60%) 29 | 9 / 142 (6.34%) 10 | |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 67 / 141 (47.52%) 260 | 54 / 142 (38.03%) 159 | |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 23 / 141 (16.31%) 51 | 18 / 142 (12.68%) 52 | |
| Neutropenia subjects affected / exposed occurrences (all) | 30 / 141 (21.28%) 73 | 31 / 142 (21.83%) 62 | |
| Gastrointestinal disorders | | | |
| Nausea subjects affected / exposed occurrences (all) | 73 / 141 (51.77%) 138 | 68 / 142 (47.89%) 130 | |
| Diarrhoea | | | |

| | | | |
|--|-------------------|-------------------|--|
| subjects affected / exposed | 90 / 141 (63.83%) | 81 / 142 (57.04%) | |
| occurrences (all) | 214 | 177 | |
| Stomatitis | | | |
| subjects affected / exposed | 25 / 141 (17.73%) | 25 / 142 (17.61%) | |
| occurrences (all) | 37 | 34 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 15 / 141 (10.64%) | 16 / 142 (11.27%) | |
| occurrences (all) | 16 | 20 | |
| Abdominal pain | | | |
| subjects affected / exposed | 36 / 141 (25.53%) | 34 / 142 (23.94%) | |
| occurrences (all) | 68 | 55 | |
| Vomiting | | | |
| subjects affected / exposed | 40 / 141 (28.37%) | 38 / 142 (26.76%) | |
| occurrences (all) | 67 | 58 | |
| Constipation | | | |
| subjects affected / exposed | 39 / 141 (27.66%) | 38 / 142 (26.76%) | |
| occurrences (all) | 60 | 56 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 10 / 141 (7.09%) | 7 / 142 (4.93%) | |
| occurrences (all) | 12 | 9 | |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 4 / 141 (2.84%) | 9 / 142 (6.34%) | |
| occurrences (all) | 6 | 9 | |
| Abdominal distension | | | |
| subjects affected / exposed | 10 / 141 (7.09%) | 13 / 142 (9.15%) | |
| occurrences (all) | 10 | 15 | |
| Dyspepsia | | | |
| subjects affected / exposed | 6 / 141 (4.26%) | 11 / 142 (7.75%) | |
| occurrences (all) | 8 | 12 | |
| Dry mouth | | | |
| subjects affected / exposed | 6 / 141 (4.26%) | 10 / 142 (7.04%) | |
| occurrences (all) | 8 | 11 | |
| Flatulence | | | |
| subjects affected / exposed | 6 / 141 (4.26%) | 9 / 142 (6.34%) | |
| occurrences (all) | 6 | 9 | |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|-------------------|-------------------|--|
| Alopecia subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all) Dry skin subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all) Rash maculo-papular subjects affected / exposed occurrences (all) | 57 / 141 (40.43%) | 53 / 142 (37.32%) | |
| | 69 | 62 | |
| | 11 / 141 (7.80%) | 18 / 142 (12.68%) | |
| | 12 | 22 | |
| | 6 / 141 (4.26%) | 8 / 142 (5.63%) | |
| | 11 | 8 | |
| | 17 / 141 (12.06%) | 14 / 142 (9.86%) | |
| | 21 | 25 | |
| | 12 / 141 (8.51%) | 12 / 142 (8.45%) | |
| | 20 | 17 | |
| Renal and urinary disorders | | | |
| Dysuria | | | |
| subjects affected / exposed | 10 / 141 (7.09%) | 3 / 142 (2.11%) | |
| occurrences (all) | 10 | 4 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 18 / 141 (12.77%) | 14 / 142 (9.86%) | |
| occurrences (all) | 20 | 18 | |
| Back pain | | | |
| subjects affected / exposed | 17 / 141 (12.06%) | 13 / 142 (9.15%) | |
| occurrences (all) | 21 | 14 | |
| Pain in extremity | | | |
| subjects affected / exposed | 14 / 141 (9.93%) | 6 / 142 (4.23%) | |
| occurrences (all) | 17 | 8 | |
| Muscular weakness | | | |
| subjects affected / exposed | 16 / 141 (11.35%) | 6 / 142 (4.23%) | |
| occurrences (all) | 23 | 6 | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 48 / 141 (34.04%) | 50 / 142 (35.21%) | |
| occurrences (all) | 73 | 93 | |

| | | | |
|-----------------------------|-------------------|-------------------|--|
| Hypokalaemia | | | |
| subjects affected / exposed | 33 / 141 (23.40%) | 18 / 142 (12.68%) | |
| occurrences (all) | 64 | 33 | |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 14 / 141 (9.93%) | 7 / 142 (4.93%) | |
| occurrences (all) | 36 | 10 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 9 / 141 (6.38%) | 9 / 142 (6.34%) | |
| occurrences (all) | 15 | 14 | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 6 / 141 (4.26%) | 14 / 142 (9.86%) | |
| occurrences (all) | 12 | 23 | |
| Dehydration | | | |
| subjects affected / exposed | 8 / 141 (5.67%) | 9 / 142 (6.34%) | |
| occurrences (all) | 10 | 10 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|--|
| 25 October 2021 | It included following key changes: - Updated Secondary Objective to evaluate the effect of neoadjuvant treatment with pamrevlumab in combination with gemcitabineplus nab-paclitaxel or FOLFIRINOX on EFS. - Updated endpoint for Accelerated Approval; replacing resection rate with EFS and specified details of evaluation during interim analysis. - Re-ordering of Secondary Endpoints; positioning PFS as key secondary endpoint with quality of life (QOL) endpoints next in hierarchical testing order. - Included infusion 'windows' for FOLFIRINOX dosing regimen. - Updated language to clarify use of cytochrome P (CYP) inhibitors and inducers in participants receiving nab-paclitaxel. - Added language to clarify documentation of protocol deviations due to COVID-19. |
| 16 May 2022 | It included following key changes: - Per Protocol (PP) Population was added. - Objective Response Rate (ORR) was added as a secondary endpoint and the ordering of secondary endpoints was clarified. - Revised exclusion criteria and Prohibited Concomitant Medications section. - Updated statistical methods. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported