Clinical trial results:
A Phase 1/2 Study to Evaluate the Safety, Tolerability, and Efficacy of INCB001158 in Combination With Chemotherapy, in Subjects With Advanced or Metastatic Solid Tumors

Summary

EudraCT number	2017-002904-29
Trial protocol	GB BE
Global end of trial date	28 November 2022

Results information

Result version number	v2 (current)
This version publication date	27 December 2023
First version publication date	26 October 2023
Version creation reason	• Correction of full data set Revisions made to align with revisions made to the ClinicalTrials.gov results summary to address NIH review comments.

Trial information

Trial identification

Sponsor protocol code	INCB 01158-203

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Incyte Corporation
Sponsor organisation address	1801 Augustine Cutoff Drive, Wilmington, United States,
Public contact	Study Director, Incyte Corporation, 1 855-463-3463, medinfo@incyte.com
Scientific contact	Study Director, Incyte Corporation, 1 855-463-3463, medinfo@incyte.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 November 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 November 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Phase 1: To assess the safety and tolerability and determine the recommended Phase 2 dose (RP2D) of INCB001158 in combination with chemotherapy

Phase 2: To evaluate the objective response rate (ORR) of INCB001158 in combination with chemotherapy

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 November 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 17
Country: Number of subjects enrolled	United Kingdom: 37
Country: Number of subjects enrolled	United States: 95
Worldwide total number of subjects	149
EEA total number of subjects	17

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)	92
From 65 to 84 years	55
85 years and over	2

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study was conducted at 11 study centers in the United States, the United Kingdom, and Belgium.

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	Phase 1: INCB001158 50 mg + mFOLFOX6

Arm description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 milligrams (mg) twice daily (BID) starting on Day 1 of each 28-day cycle. Participants also received intravenous modified FOLFOX6 (mFOLFOX6: oxaliplatin 85 mg/meters squared [m^2], leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Arm type	Experimental
Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen

Investigational medicinal product name	leucovorin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection, Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

administered on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158

Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

administered on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158

Investigational medicinal product name	oxaliplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:	
administered on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158	

Arm title	Phase 1: INCB001158 75 mg + mFOLFOX6
Arm description:	
In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.	
Arm type	Experimental
Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen	
Investigational medicinal product name	leucovorin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection, Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
administered on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158	
Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
administered on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158	
Investigational medicinal product name	oxaliplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
administered on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158	
Arm title	Phase 1: INCB001158 100 mg + mFOLFOX6
Arm description:	
In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.	
Arm type	Experimental

Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen

Investigational medicinal product name	leucovorin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection, Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

administered on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158

Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

administered on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158

Investigational medicinal product name	oxaliplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

administered on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158

Arm title	Phase 1: INCB001158 50 mg + Gemcitabine + Cisplatin

Arm description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle.

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

Dosage and administration details:

administered on Days 1 and 8 of each 21-day cycle

Investigational medicinal product name	cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

administered on Days 1 and 8 of each 21-day cycle

Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen

Arm title	Phase 1: INCB001158 75 mg + Gemcitabine + Cisplatin

Arm description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle.

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

Dosage and administration details:

administered on Days 1 and 8 of each 21-day cycle

Investigational medicinal product name	cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

administered on Days 1 and 8 of each 21-day cycle

Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen

Arm title	Phase 1: INCB001158 100 mg + Gemcitabine + Cisplatin

Arm description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle.

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

Dosage and administration details:

administered on Days 1 and 8 of each 21-day cycle

Investigational medicinal product name	cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:	
administered on Days 1 and 8 of each 21-day cycle	
Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen	
Arm title	Phase 1: INCB001158 50 mg + Paclitaxel
Arm description:	
In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.	
Arm type	Experimental
Investigational medicinal product name	paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
administered on Days 1, 8, and 15 of each 28-day cycle	
Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen	
Arm title	Phase 1: INCB001158 75 mg + Paclitaxel
Arm description:	
In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.	
Arm type	Experimental
Investigational medicinal product name	paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
administered on Days 1, 8, and 15 of each 28-day cycle	
Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen	
Arm title	Phase 1: INCB001158 100 mg + Paclitaxel

Arm description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

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

Dosage and administration details:

administered on Days 1, 8, and 15 of each 28-day cycle

Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen

Arm title	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)

Arm description:

In Phase 2, participants with microsatellite-stable-colorectal cancer (MSS-CRC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Arm type	Experimental
Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen

Investigational medicinal product name	leucovorin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection, Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

administered on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158

Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

administered on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158

Investigational medicinal product name	oxaliplatin
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

administered on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158

Arm title	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)

Arm description:

In Phase 2, participants with biliary tract cancer (BTC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 25 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Arm type	Experimental
Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen

Investigational medicinal product name	cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

administered on Days 1 and 8 of each 21-day cycle

Investigational medicinal product name	gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

administered on Days 1 and 8 of each 21-day cycle

Arm title	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)

Arm description:

In Phase 2, participants with ovarian cancer (OC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 750 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Arm type	Experimental
Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen

Investigational medicinal product name	cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details: administered on Days 1 and 8 of each 21-day cycle	
Investigational medicinal product name	gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: administered on Days 1 and 8 of each 21-day cycle	
Arm title	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)
Arm description: In Phase 2, participants with gastroesophageal cancer (GC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.	
Arm type	Experimental
Investigational medicinal product name	paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: administered on Days 1, 8, and 15 of each 28-day cycle	
Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen	
Arm title	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)
Arm description: In Phase 2, participants with endometrial cancer (EC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.	
Arm type	Experimental
Investigational medicinal product name	paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: administered on Days 1, 8, and 15 of each 28-day cycle	
Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen	
Arm title	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)

Arm description:

In Phase 2, participants with ovarian cancer (OC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

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

Dosage and administration details:

administered on Days 1, 8, and 15 of each 28-day cycle

Investigational medicinal product name	INCB001158
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Phase 1: administered orally BID as 25 mg or 100 mg tablets; Phase 2: administered orally in 28- or 21-day cycles depending on the chemotherapy regimen

Number of subjects in period 1	Phase 1: INCB001158 50 mg + mFOLFOX6	Phase 1: INCB001158 75 mg + mFOLFOX6	Phase 1: INCB001158 100 mg + mFOLFOX6
Started	8	6	6
Completed	0	0	0
Not completed	8	6	6
Adverse event, serious fatal	4	2	5
Consent withdrawn by subject	2	1	1
Progressive Disease	2	-	-
Captured as "Other" in Database	-	2	-
Study Terminated by Sponsor	-	1	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 1: INCB001158 50 mg + Gemcitabine + Cisplatin	Phase 1: INCB001158 75 mg + Gemcitabine + Cisplatin	Phase 1: INCB001158 100 mg + Gemcitabine + Cisplatin
Started	7	4	4
Completed	0	0	0
Not completed	7	4	4
Adverse event, serious fatal	4	3	4
Consent withdrawn by subject	2	1	-
Progressive Disease	1	-	-
Captured as "Other" in Database	-	-	-
Study Terminated by Sponsor	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 1: INCB001158 50 mg + Paclitaxel	Phase 1: INCB001158 75 mg + Paclitaxel	Phase 1: INCB001158 100 mg + Paclitaxel
Started	7	5	7
Completed	0	0	0
Not completed	7	5	7
Adverse event, serious fatal	5	4	3
Consent withdrawn by subject	1	-	1
Progressive Disease	-	-	-
Captured as "Other" in Database	1	1	1
Study Terminated by Sponsor	-	-	1
Lost to follow-up	-	-	1

Number of subjects in period 1	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)
Started	8	33	9
Completed	0	0	0
Not completed	8	33	9
Adverse event, serious fatal	5	20	6
Consent withdrawn by subject	1	4	-
Progressive Disease	1	1	1
Captured as "Other" in Database	-	1	-
Study Terminated by Sponsor	-	7	2
Lost to follow-up	1	-	-

Number of subjects in period 1	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)
Started	11	10	24
Completed	0	0	0
Not completed	11	10	24
Adverse event, serious fatal	7	6	17
Consent withdrawn by subject	1	-	1
Progressive Disease	2	-	1
Captured as "Other" in Database	-	-	-
Study Terminated by Sponsor	1	4	4
Lost to follow-up	-	-	1

Reporting groups

Reporting group title	Phase 1: INCB001158 50 mg + mFOLFOX6

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 milligrams (mg) twice daily (BID) starting on Day 1 of each 28-day cycle. Participants also received intravenous modified FOLFOX6 (mFOLFOX6: oxaliplatin 85 mg/meters squared [m^2], leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Reporting group title	Phase 1: INCB001158 75 mg + mFOLFOX6

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Reporting group title	Phase 1: INCB001158 100 mg + mFOLFOX6

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Reporting group title	Phase 1: INCB001158 50 mg + Gemcitabine + Cisplatin

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle.

Reporting group title	Phase 1: INCB001158 75 mg + Gemcitabine + Cisplatin

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle.

Reporting group title	Phase 1: INCB001158 100 mg + Gemcitabine + Cisplatin

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle.

Reporting group title	Phase 1: INCB001158 50 mg + Paclitaxel

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Phase 1: INCB001158 75 mg + Paclitaxel

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Phase 1: INCB001158 100 mg + Paclitaxel

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)

Reporting group description:

In Phase 2, participants with microsatellite-stable-colorectal cancer (MSS-CRC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous

mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Reporting group title	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)

Reporting group description:

In Phase 2, participants with biliary tract cancer (BTC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 25 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Reporting group title	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)

Reporting group description:

In Phase 2, participants with ovarian cancer (OC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 750 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Reporting group title	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)

Reporting group description:

In Phase 2, participants with gastroesophageal cancer (GC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)

Reporting group description:

In Phase 2, participants with endometrial cancer (EC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)

Reporting group description:

In Phase 2, participants with ovarian cancer (OC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group values	Phase 1: INCB001158 50 mg + mFOLFOX6	Phase 1: INCB001158 75 mg + mFOLFOX6	Phase 1: INCB001158 100 mg + mFOLFOX6
Number of subjects	8	6	6
Age categorical Units: Subjects			
Adults (18-64 years)	6	4	2
From 65-84 years	2	2	4
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	56.4	60.3	65.2
standard deviation	± 10.80	± 9.93	± 7.99
Sex: Female, Male Units: participants			
Female	3	4	3
Male	5	2	3
Race/Ethnicity, Customized Units: Subjects			
White	2	6	6
Black/African-American	2	0	0
Asian	1	0	0
American-Indian/Alaska Native	0	0	0
East Indian	1	0	0

Not Provided/Specified	1	0	0
Black/Carribean	1	0	0
Captured as Hispanic/Latino in Database	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	5	5	6
Unknown or Not Reported	3	0	0

Reporting group values	Phase 1: INCB001158 50 mg + Gemcitabine + Cisplatin	Phase 1: INCB001158 75 mg + Gemcitabine + Cisplatin	Phase 1: INCB001158 100 mg + Gemcitabine + Cisplatin
Number of subjects	7	4	4
Age categorical Units: Subjects			
Adults (18-64 years)	4	3	3
From 65-84 years	3	0	1
85 years and over	0	1	0
Age Continuous Units: years			
arithmetic mean	54.0	64.5	54.0
standard deviation	± 18.93	± 16.82	± 15.64
Sex: Female, Male Units: participants			
Female	3	2	3
Male	4	2	1
Race/Ethnicity, Customized Units: Subjects			
White	6	3	4
Black/African-American	0	0	0
Asian	0	1	0
American-Indian/Alaska Native	0	0	0
East Indian	0	0	0
Not Provided/Specified	0	0	0
Black/Carribean	0	0	0
Captured as Hispanic/Latino in Database	1	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	6	4	4
Unknown or Not Reported	0	0	0

Reporting group values	Phase 1: INCB001158 50 mg + Paclitaxel	Phase 1: INCB001158 75 mg + Paclitaxel	Phase 1: INCB001158 100 mg + Paclitaxel
Number of subjects	7	5	7
Age categorical Units: Subjects			
Adults (18-64 years)	4	5	4
From 65-84 years	2	0	3
85 years and over	1	0	0

Age Continuous Units: years			
arithmetic mean	62.0	47.4	61.4
standard deviation	± 14.57	± 10.29	± 6.95
Sex: Female, Male Units: participants			
Female	5	4	5
Male	2	1	2
Race/Ethnicity, Customized Units: Subjects			
White	7	5	5
Black/African-American	0	0	1
Asian	0	0	1
American-Indian/Alaska Native	0	0	0
East Indian	0	0	0
Not Provided/Specified	0	0	0
Black/Carribean	0	0	0
Captured as Hispanic/Latino in Database	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	7	5	7
Unknown or Not Reported	0	0	0

Reporting group values	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)
Number of subjects	8	33	9
Age categorical Units: Subjects			
Adults (18-64 years)	3	19	5
From 65-84 years	5	14	4
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	62.8	59.3	65.3
standard deviation	± 11.26	± 12.74	± 8.87
Sex: Female, Male Units: participants			
Female	3	21	9
Male	5	12	0
Race/Ethnicity, Customized Units: Subjects			
White	7	31	8
Black/African-American	1	1	0
Asian	0	0	0
American-Indian/Alaska Native	0	0	1
East Indian	0	0	0
Not Provided/Specified	0	1	0
Black/Carribean	0	0	0

Captured as Hispanic/Latino in Database	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	2	1
Not Hispanic or Latino	7	29	7
Unknown or Not Reported	0	2	1

Reporting group values	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)
Number of subjects	11	10	24
Age categorical Units: Subjects			
Adults (18-64 years)	8	7	15
From 65-84 years	3	3	9
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	58.8	62.3	60.6
standard deviation	± 11.90	± 9.29	± 9.04
Sex: Female, Male Units: participants			
Female	4	10	24
Male	7	0	0
Race/Ethnicity, Customized Units: Subjects			
White	8	8	23
Black/African-American	0	1	0
Asian	2	1	1
American-Indian/Alaska Native	0	0	0
East Indian	0	0	0
Not Provided/Specified	1	0	0
Black/Carribean	0	0	0
Captured as Hispanic/Latino in Database	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	11	10	23
Unknown or Not Reported	0	0	1

Reporting group values	Total		
Number of subjects	149		
Age categorical Units: Subjects			
Adults (18-64 years)	92		
From 65-84 years	55		
85 years and over	2		
Age Continuous Units: years			
arithmetic mean			

standard deviation	-		

Sex: Female, Male Units: participants			
Female	103		
Male	46		
Race/Ethnicity, Customized Units: Subjects			
White	129		
Black/African-American	6		
Asian	7		
American-Indian/Alaska Native	1		
East Indian	1		
Not Provided/Specified	3		
Black/Carribean	1		
Captured as Hispanic/Latino in Database	1		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	6		
Not Hispanic or Latino	136		
Unknown or Not Reported	7		

End points

End points reporting groups

Reporting group title	Phase 1: INCB001158 50 mg + mFOLFOX6

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 milligrams (mg) twice daily (BID) starting on Day 1 of each 28-day cycle. Participants also received intravenous modified FOLFOX6 (mFOLFOX6: oxaliplatin 85 mg/meters squared [m^2], leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Reporting group title	Phase 1: INCB001158 75 mg + mFOLFOX6

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Reporting group title	Phase 1: INCB001158 100 mg + mFOLFOX6

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Reporting group title	Phase 1: INCB001158 50 mg + Gemcitabine + Cisplatin

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle.

Reporting group title	Phase 1: INCB001158 75 mg + Gemcitabine + Cisplatin

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle.

Reporting group title	Phase 1: INCB001158 100 mg + Gemcitabine + Cisplatin

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle.

Reporting group title	Phase 1: INCB001158 50 mg + Paclitaxel

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Phase 1: INCB001158 75 mg + Paclitaxel

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Phase 1: INCB001158 100 mg + Paclitaxel

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)

Reporting group description:

In Phase 2, participants with microsatellite-stable-colorectal cancer (MSS-CRC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous

mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Reporting group title	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)

Reporting group description:

In Phase 2, participants with biliary tract cancer (BTC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 25 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Reporting group title	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)

Reporting group description:

In Phase 2, participants with ovarian cancer (OC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 750 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Reporting group title	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)

Reporting group description:

In Phase 2, participants with gastroesophageal cancer (GC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)

Reporting group description:

In Phase 2, participants with endometrial cancer (EC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)

Reporting group description:

In Phase 2, participants with ovarian cancer (OC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Subject analysis set title	Phase 1 and Phase 2: INCB001158 50 mg + mFOLFOX6
Subject analysis set type	Full analysis

Subject analysis set description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 mg BID starting on Day 1 of each 28-day cycle. In Phases 1 and 2, participants with advanced or metastatic solid tumors (Phase 1) and MSS-CRC (Phase 2) also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Subject analysis set title	Phase 1 and Phase 2: INCB001158 75 mg + mFOLFOX6
Subject analysis set type	Full analysis

Subject analysis set description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. In Phases 1 and 2, participants with advanced or solid metastatic tumors (Phase 1) and MSS-CRC (Phase 2) also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Subject analysis set title	Phase 1 and Phase 2: INCB001158 100 mg + mFOLFOX6
Subject analysis set type	Full analysis

Subject analysis set description:

In Phases 1 and 2, participants with advanced or metastatic solid tumors (Phase 1) and MSS-CRC (Phase 2) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Subject analysis set title	Phase 1 and Phase 2: INCB001158 50 mg+Gemcitabine+Cisplatin
Subject analysis set type	Full analysis

Subject analysis set description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000

mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle. In Phase 2, participants with BTC received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 25 mg/m^2 on Day 1 and 8 of each 28-day cycle, and participants with OC received intravenous gemcitabine 750 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Subject analysis set title	Phase 1 and Phase 2: INCB001158 75 mg+Gemcitabine+Cisplatin
Subject analysis set type	Full analysis

Subject analysis set description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle. In Phase 2, participants with BTC received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 25 mg/m^2 on Day 1 and 8 of each 28-day cycle, and participants with OC received intravenous gemcitabine 750 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Subject analysis set title	Phase 1 and Phase 2: INCB001158 100 mg+Gemcitabine+Cisplatin
Subject analysis set type	Full analysis

Subject analysis set description:

In Phases 1 and 2, participants with advanced or metastatic solid tumors (Phase 1) and with BTC or OC (Phase 2) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. In Phase 1, participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle. In Phase 2, participants with BTC received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 25 mg/m^2 on Day 1 and 8 of each 28-day cycle, and participants with OC received intravenous gemcitabine 750 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Subject analysis set title	Phase 1 and Phase 2: INCB001158 50 mg + Paclitaxel
Subject analysis set type	Full analysis

Subject analysis set description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 mg BID starting on Day 1 of each 28-day cycle. In Phases 1 and 2, participants with advanced or metastatic solid tumors (Phase 1) and with GC, EC, or OC (Phase 2) received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Subject analysis set title	Phase 1 and Phase 2: INCB001158 75 mg + Paclitaxel
Subject analysis set type	Full analysis

Subject analysis set description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. In Phases 1 and 2, participants with advanced or metastatic solid tumors (Phase 1) and with GC, EC, or OC (Phase 2) received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Subject analysis set title	Phase 1 and Phase 2: INCB001158 100 mg + Paclitaxel
Subject analysis set type	Full analysis

Subject analysis set description:

In Phases 1 and 2, participants with advanced or metastatic solid tumors (Phase 1) and GC, EC, or OC (Phase 2) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants with advanced or metastatic solid tumors (Phase 1) and with GC, EC, or OC (Phase 2) also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Subject analysis set title	All Phase 1 Participants
Subject analysis set type	Full analysis

Subject analysis set description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50, 75, or 100 mg BID plus intravenous modified FOLFOX6, intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2, or intravenous paclitaxel 80 mg/m^2.

Subject analysis set title	Phase 1 and Phase 2: INCB001158 75 mg + mFOLFOX6 (Cohort B1)
Subject analysis set type	Full analysis

Subject analysis set description:

In Phase 2, for Pharmacokinetic (PK) analysis, participants with biliary tract cancer (BTC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 25 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Subject analysis set title	Phase 1 and Phase 2: INCB001158 75 mg + mFOLFOX6 (Cohort B1)

Subject analysis set type	Full analysis

Subject analysis set description:

In Phase 2, for PK analysis, participants with biliary tract cancer (BTC) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 25 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Primary: Phases 1 and 2: Number of participants with any treatment-emergent adverse event (TEAE)

End point title	Phases 1 and 2: Number of participants with any treatment-emergent adverse event (TEAE)[1]

End point description:

An adverse event (AE) was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related, that occurred after a participant provided informed consent. Abnormal laboratory values or test results occurring after informed consent constituted AEs only if they induced clinical signs or symptoms, were considered clinically meaningful, required therapy (e.g., hematologic abnormality that required transfusion), or required changes in the study drug(s). A TEAE was defined as any AE either reported for the first time or the worsening of a pre-existing event after the first dose of study drug. As pre-defined in the Statistical Analysis Plan, data analysis was conducted based on treatment group and dose level, regardless of study phase, because the safety profile was expected to be generally uniform across tumor types.

End point type	Primary

End point timeframe:

up to 1385 days

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not conducted for this endpoint.

End point values	Phase 1 and Phase 2: INCB001158 50 mg + mFOLFOX6	Phase 1 and Phase 2: INCB001158 75 mg + mFOLFOX6	Phase 1 and Phase 2: INCB001158 100 mg + mFOLFOX6	Phase 1 and Phase 2: INCB001158 50 mg+Gemcitabine+Cisplatin
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	6	14	7
Units: participants	8	6	13	7

End point values	Phase 1 and Phase 2: INCB001158 75 mg+Gemcitabine+Cisplatin	Phase 1 and Phase 2: INCB001158 100 mg+Gemcitabine+Cisplatin	Phase 1 and Phase 2: INCB001158 50 mg + Paclitaxel	Phase 1 and Phase 2: INCB001158 75 mg + Paclitaxel
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	46	7	5
Units: participants	4	46	7	5

End point values	Phase 1 and Phase 2: INCB001158 100 mg + Paclitaxel			

Subject group type	Subject analysis set			
Number of subjects analysed	52			
Units: participants	51			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Number of participants with any dose-limiting toxicity (DLT)

End point title	Phase 1: Number of participants with any dose-limiting toxicity (DLT)[2][3]

End point description:

A DLT was defined as the occurrence of any protocol-defined toxicity occurring up to and including Day 28, except those with a clear alternative explanation (e.g., disease progression) or transient (≤72 hours) abnormal laboratory values without associated clinically significant signs or symptoms based on investigator determination. All DLTs were assessed by the investigator using Common Terminology Criteria for Adverse Events (CTCAE) v4.03 criteria.

End point type	Primary

End point timeframe:

up to Day 28

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not conducted for this endpoint.

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not conducted for this endpoint.

End point values	Phase 1: INCB001158 50 mg + mFOLFOX6	Phase 1: INCB001158 75 mg + mFOLFOX6	Phase 1: INCB001158 100 mg + mFOLFOX6	Phase 1: INCB001158 50 mg + Gemcitabine + Cisplatin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	6	6	7
Units: participants	0	0	0	1

End point values	Phase 1: INCB001158 75 mg + Gemcitabine + Cisplatin	Phase 1: INCB001158 100 mg + Gemcitabine + Cisplatin	Phase 1: INCB001158 50 mg + Paclitaxel	Phase 1: INCB001158 75 mg + Paclitaxel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	5
Units: participants	0	0	0	0

End point values	Phase 1: INCB001158 100 mg +			

	Paclitaxel			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: participants	0			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Objective Response Rate (ORR)

End point title	Phase 2: Objective Response Rate (ORR)[4][5]

End point description:

ORR was defined as the percentage of participants with a best overall response of complete response (CR) or partial response (PR), as determined by investigator assessment of radiographic disease as per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 (v1.1). CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 millimeters (mm). PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. Analysis was conducted by cohort (tumor type) in Phase 2 because different tumor types could have different response criteria or different background response rates.

End point type	Primary

End point timeframe:

up to 1385 days

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not conducted for this endpoint.

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not conducted for this endpoint.

End point values	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	33	9	11
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 36.9)	24.2 (11.1 to 42.3)	22.2 (2.8 to 60.0)	9.1 (0.2 to 41.3)

End point values	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	24		

Units: percentage of participants				
number (confidence interval 95%)	30.0 (6.7 to 65.2)	16.7 (4.7 to 37.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Recommended Phase 2 dose (RP2D) of INCB001158 when given in combination with each chemotherapy regimen

End point title	Recommended Phase 2 dose (RP2D) of INCB001158 when given in combination with each chemotherapy regimen[6]

End point description:

The RP2D of the combination of INCB001158 and chemotherapy in 21-day (for gemcitabine/cisplatin) or 28-day (for mFOLFOX6 or paclitaxel) treatment cycles in participants with advanced or metastatic solid tumors was determined. After the dose escalation was completed, the INCB001158 dose level that was pharmacologically active and tolerable in combination with each chemotherapy regimen (i.e., maximum tolerated dose or lower) was determined to be the RP2D. The RP2D was then further assessed in tumor expansion cohorts in Phase 2.

End point type	Primary

End point timeframe:

up to Day 580

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not conducted for this endpoint.

End point values	All Phase 1 Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: milligrams	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: ORR

End point title	Phase 1: ORR[7]

End point description:

ORR was defined as the percentage of participants with a confirmed best overall response of CR or PR, as determined by investigator assessment of radiographic disease as per RECIST v1.1. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the Baseline sum diameters, no new lesions, and no progression of non-target lesions.

End point type	Secondary

End point timeframe:

up to 580 days

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not conducted for this endpoint.

End point values	Phase 1: INCB001158 50 mg + mFOLFOX6	Phase 1: INCB001158 75 mg + mFOLFOX6	Phase 1: INCB001158 100 mg + mFOLFOX6	Phase 1: INCB001158 50 mg + Gemcitabine + Cisplatin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	6	6	7
Units: percentage of participants				
number (confidence interval 95%)	12.5 (0.3 to 52.7)	0.0 (0.0 to 45.9)	0.0 (0.0 to 45.9)	0.0 (0.0 to 41.0)

End point values	Phase 1: INCB001158 75 mg + Gemcitabine + Cisplatin	Phase 1: INCB001158 100 mg + Gemcitabine + Cisplatin	Phase 1: INCB001158 50 mg + Paclitaxel	Phase 1: INCB001158 75 mg + Paclitaxel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	5
Units: percentage of participants				
number (confidence interval 95%)	25.0 (0.6 to 80.6)	0.0 (0.0 to 60.2)	14.3 (0.4 to 57.9)	0.0 (0.0 to 52.2)

End point values	Phase 1: INCB001158 100 mg + Paclitaxel			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: percentage of participants				
number (confidence interval 95%)	28.6 (3.7 to 71.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phases 1 and 2: Duration of Response

End point title	Phases 1 and 2: Duration of Response

End point description:

DOR was defined as the time from initial objective response (CR or PR) (as determined by investigator assessment of radiographic disease assessment per RECIST v1.1) until the earliest date of disease progression or death due to any cause, if it occurred sooner than disease progression. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target

lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. 9999=the upper limit of the confidence interval was not estimable because too few participants had disease progression or died. The Kaplan Meier estimation method on a sample size of less than 5 responders is not valid.

End point type	Secondary

End point timeframe:

up to 368 days

End point values	Phase 1: INCB001158 50 mg + mFOLFOX6	Phase 1: INCB001158 75 mg + mFOLFOX6	Phase 1: INCB001158 100 mg + mFOLFOX6	Phase 1: INCB001158 50 mg + Gemcitabine + Cisplatin
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] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

[9] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

[10] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

[11] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

End point values	Phase 1: INCB001158 75 mg + Gemcitabine + Cisplatin	Phase 1: INCB001158 100 mg + Gemcitabine + Cisplatin	Phase 1: INCB001158 50 mg + Paclitaxel	Phase 1: INCB001158 75 mg + Paclitaxel
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] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

[13] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

[14] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

[15] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

End point values	Phase 1: INCB001158 100 mg + Paclitaxel	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[16]	0[17]	8	0[18]
Units: months				
median (confidence interval 95%)	(to)	(to)	5.8 (4.1 to 9999)	(to)

Notes:

[16] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

[17] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

[18] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

End point values	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[19]	0[20]	0[21]	
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[19] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

[20] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

[21] - Duration of response was analyzed in cohorts with >5 objective responders (CR or PR).

Statistical analyses

No statistical analyses for this end point

Secondary: Phases 1 and 2: Disease Control Rate

End point title	Phases 1 and 2: Disease Control Rate

End point description:

DCR was defined as the percentage of participants with an overall response of CR, PR, or stable disease (SD), as determined by investigator assessment of radiographic disease as per RECIST v1.1, for at least 8 weeks. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. SD: no change in target lesions to qualify for CR, PR, or PD.

End point type	Secondary

End point timeframe:

up to 1385 days

End point values	Phase 1: INCB001158 50 mg + mFOLFOX6	Phase 1: INCB001158 75 mg + mFOLFOX6	Phase 1: INCB001158 100 mg + mFOLFOX6	Phase 1: INCB001158 50 mg + Gemcitabine + Cisplatin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	6	6	7
Units: percentage of participants				
number (confidence interval 95%)	62.5 (24.5 to 91.5)	83.3 (35.9 to 99.6)	16.7 (0.4 to 64.1)	57.1 (18.4 to 90.1)

End point values	Phase 1: INCB001158 75 mg + Gemcitabine +	Phase 1: INCB001158 100 mg + Gemcitabine +	Phase 1: INCB001158 50 mg + Paclitaxel	Phase 1: INCB001158 75 mg + Paclitaxel

	Cisplatin	Cisplatin		
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	5
Units: percentage of participants				
number (confidence interval 95%)	75.0 (19.4 to 99.4)	100.0 (39.8 to 100.0)	42.9 (9.9 to 81.6)	60.0 (14.7 to 94.7)

End point values	Phase 1: INCB001158 100 mg + Paclitaxel	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	33	9
Units: percentage of participants				
number (confidence interval 95%)	85.7 (42.1 to 99.6)	100.0 (63.1 to 100.0)	66.7 (48.2 to 82.0)	88.9 (51.8 to 99.7)

End point values	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	10	24	
Units: percentage of participants				
number (confidence interval 95%)	54.5 (23.4 to 83.3)	80.0 (44.4 to 97.5)	66.7 (44.7 to 84.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phases 1 and 2: Progression-free Survival

End point title	Phases 1 and 2: Progression-free Survival

End point description:

According to RECIST 1.1, PFS was defined as the length of time from the date of the first dose study of drug until the earliest date of disease progression, as determined by investigator assessment of radiographic disease per RECIST v1.1, or death due to any cause, if it occurred sooner than progression. -9999, 9999=the upper and lower limits of the confidence interval were not estimable because too few participants had disease progression or died.

End point type	Secondary

End point timeframe:

up to 1385 days

End point values	Phase 1: INCB001158 50 mg + mFOLFOX6	Phase 1: INCB001158 75 mg + mFOLFOX6	Phase 1: INCB001158 100 mg + mFOLFOX6	Phase 1: INCB001158 50 mg + Gemcitabine + Cisplatin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	6	6	7
Units: months				
median (confidence interval 95%)	3.7 (1.8 to 3.9)	6.6 (1.7 to 9999)	1.7 (1.6 to 9999)	3.9 (0.6 to 9999)

End point values	Phase 1: INCB001158 75 mg + Gemcitabine + Cisplatin	Phase 1: INCB001158 100 mg + Gemcitabine + Cisplatin	Phase 1: INCB001158 50 mg + Paclitaxel	Phase 1: INCB001158 75 mg + Paclitaxel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	5
Units: months				
median (confidence interval 95%)	5.3 (-9999 to 9999)	6.4 (3.7 to 9999)	3.9 (0.8 to 9999)	3.7 (1.5 to 9999)

End point values	Phase 1: INCB001158 100 mg + Paclitaxel	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	33	9
Units: months				
median (confidence interval 95%)	11.8 (1.7 to 16.1)	3.7 (2.8 to 9999)	8.5 (5.7 to 10.1)	7.8 (2.2 to 9999)

End point values	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	10	24	
Units: months				
median (confidence interval 95%)	3.5 (1.7 to 9999)	7.1 (3.5 to 11.1)	3.7 (2.4 to 4.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cmin of INCB001158 in participants treated with INCB001158 in combination with chemotherapy on Cycle 2 Day 1 following repeated dose administration

End point title	Cmin of INCB001158 in participants treated with INCB001158 in combination with chemotherapy on Cycle 2 Day 1 following repeated dose administration[22]

End point description:

Cmin was defined as the minimum observed plasma concentration over the dose interval. Extensive sample collection was used for the first 12 participants enrolled in each chemotherapy regimen. Sparse sample collection was used for the 13th participant enrolled and onward.

End point type	Secondary

End point timeframe:

Day 1 of Cycle 2: predose; 0.5, 1, 2, 4, 6, and 8-10 hours post-dose for extensive sample collection.
Day 1 of Cycle 2: predose; 1 and 4 hours post-dose for sparse sample collection

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not conducted for this endpoint.

End point values	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7[23]	17[24]	8[25]	8[26]
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	747 (± 35.7)	407 (± 407)	268 (± 888)	542 (± 102)

Notes:

[23] - Only participants with available data were analyzed.

[24] - Only participants with available data were analyzed.

[25] - Only participants with available data were analyzed.

[26] - Only participants with available data were analyzed.

End point values	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5[27]	13[28]		
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient	1020 (± 27.2)	633 (± 131)		

of variation)

Notes:

[27] - Only participants with available data were analyzed.

[28] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of INCB001158 in participants treated with INCB001158 in combination with chemotherapy following the first dose on Cycle 1 Day 1 and on Cycle 2 Day 1 following repeated dose administration

End point title	Cmax of INCB001158 in participants treated with INCB001158 in combination with chemotherapy following the first dose on Cycle 1 Day 1 and on Cycle 2 Day 1 following repeated dose administration[29]

End point description:

Cmax was defined as the maximum observed plasma concentration over the dose interval. Extensive sample collection was used for the first 12 participants enrolled in each chemotherapy regimen. Sparse sample collection was used for the 13th participant enrolled and onward.

End point type	Secondary

End point timeframe:

Day 1 of Cycles 1 and 2: predose; 0.5, 1, 2, 4, 6, and 8-10 hours post-dose for extensive sample collection. Day 1 of Cycles 1 and 2: predose; 1 and 4 hours post-dose for sparse sample collection

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not conducted for this endpoint.

End point values	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8[30]	18[31]	9[32]	10[33]
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1, n=8, 18, 9, 10, 6, 15	1290 (± 16.4)	1350 (± 35.2)	2160 (± 22.3)	1100 (± 68.0)
Cycle 2 Day 1, n=7, 17, 8, 8, 5, 13	1960 (± 12.6)	1860 (± 46.7)	2250 (± 26.4)	1600 (± 22.0)

Notes:

[30] - Only participants with available data were analyzed.

[31] - Only participants with available data were analyzed.

[32] - Only participants with available data were analyzed.

[33] - Only participants with available data were analyzed.

End point values	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[34]	15[35]		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1, n=8, 18, 9, 10, 6, 15	1760 (± 17.2)	1640 (± 23.2)		
Cycle 2 Day 1, n=7, 17, 8, 8, 5, 13	2390 (± 11.4)	2100 (± 24.6)		

Notes:

[34] - Only participants with available data were analyzed.

[35] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: tmax of INCB001158 in participants treated with INCB001158 in combination with chemotherapy following the first dose on Cycle 1 Day 1 and on Cycle 2 Day 1 following repeated dose administration

End point title	tmax of INCB001158 in participants treated with INCB001158 in combination with chemotherapy following the first dose on Cycle 1 Day 1 and on Cycle 2 Day 1 following repeated dose administration[36]

End point description:

tmax was defined as the time to the maximum concentration. Extensive sample collection was used for the first 12 participants enrolled in each chemotherapy regimen. Sparse sample collection was used for the 13th participant enrolled and onward.

End point type	Secondary

End point timeframe:

Day 1 of Cycles 1 and 2: predose; 0.5, 1, 2, 4, 6, and 8-10 hours post-dose for extensive sample collection. Day 1 of Cycles 1 and 2: predose; 1 and 4 hours post-dose for sparse sample collection

Notes:

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not conducted for this endpoint.

End point values	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8[37]	18[38]	9[39]	10[40]
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1, n=8, 18, 9, 10, 6, 15	4.13 (2.00 to 6.10)	4.07 (1.97 to 7.53)	4.08 (3.67 to 6.00)	5.05 (2.25 to 7.50)
Cycle 2 Day 1, n=7, 17, 8, 8, 5, 13	4.00 (1.80 to 7.50)	4.00 (0.983 to 7.53)	4.06 (2.03 to 6.02)	4.13 (1.92 to 7.53)

Notes:

[37] - Only participants with available data were analyzed.

[38] - Only participants with available data were analyzed.

[39] - Only participants with available data were analyzed.

[40] - Only participants with available data were analyzed.

End point values	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[41]	15[42]		
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1, n=8, 18, 9, 10, 6, 15	4.09 (2.00 to 6.17)	3.97 (1.78 to 6.08)		
Cycle 2 Day 1, n=7, 17, 8, 8, 5, 13	3.85 (3.77 to 3.92)	3.95 (2.03 to 6.00)		

Notes:

[41] - Only participants with available data were analyzed.

[42] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC0-t of INCB001158 in participants treated with INCB001158 in combination with chemotherapy following the first dose on Cycle 1 Day 1 and on Cycle 2 Day 1 following repeated dose administration

End point title	AUC0-t of INCB001158 in participants treated with INCB001158 in combination with chemotherapy following the first dose on Cycle 1 Day 1 and on Cycle 2 Day 1 following repeated dose administration[43]

End point description:

AUC0-t was defined as the area under the plasma concentration-time curve from time = 0 to the last measurable concentration at time = t. Extensive sample collection was used for the first 12 participants enrolled in each chemotherapy regimen. Sparse sample collection was used for the 13th participant enrolled and onward.

End point type	Secondary

End point timeframe:

Day 1 of Cycles 1 and 2: predose; 0.5, 1, 2, 4, 6, and 8-10 hours post-dose for extensive sample collection. Day 1 of Cycles 1 and 2: predose; 1 and 4 hours post-dose for sparse sample collection

Notes:

[43] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not conducted for this endpoint.

End point values	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8[44]	18[45]	9[46]	10[47]
Units: hours x ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1, n=8, 18, 9, 10, 6, 15	6910 (± 17.6)	7240 (± 32.9)	10600 (± 18.9)	4680 (± 134)
Cycle 2 Day 1, n=7, 17, 8, 8, 5, 13	11000 (± 21.1)	10600 (± 55.3)	12200 (± 34.4)	10000 (± 18.4)

Notes:

[44] - Only participants with available data were analyzed.

[45] - Only participants with available data were analyzed.

[46] - Only participants with available data were analyzed.

[47] - Only participants with available data were analyzed.

End point values	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[48]	15[49]		
Units: hours x ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1, n=8, 18, 9, 10, 6, 15	9290 (± 33.2)	8840 (± 24.7)		
Cycle 2 Day 1, n=7, 17, 8, 8, 5, 13	14400 (± 13.7)	12800 (± 30.3)		

Notes:

[48] - Only participants with available data were analyzed.

[49] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: tlast of INCB001158 in participants treated with INCB001158 in combination with chemotherapy following the first dose on Cycle 1 Day 1 and on Cycle 2 Day 1 following repeated dose administration

End point title	tlast of INCB001158 in participants treated with INCB001158 in combination with chemotherapy following the first dose on Cycle 1 Day 1 and on Cycle 2 Day 1 following repeated dose administration[50]

End point description:

tlast was defined as the time of the last sample collected from which a concentration was measured. Extensive sample collection was used for the first 12 participants enrolled in each chemotherapy regimen. Sparse sample collection was used for the 13th participant enrolled and onward.

End point type	Secondary

End point timeframe:

Day 1 of Cycles 1 and 2: predose; 0.5, 1, 2, 4, 6, and 8-10 hours post-dose for extensive sample collection. Day 1 of Cycles 1 and 2: predose; 1 and 4 hours post-dose for sparse sample collection

Notes:

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not conducted for this endpoint.

End point values	Phase 2: INCB001158 100 mg + mFOLFOX6: MSS-CRC (Cohort A1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: BTC (Cohort B1)	Ph 2: INCB001158 100 mg+Gemcitabine+Cisplatin: OC (Cohort B2)	Phase 2: INCB001158 100 mg + Paclitaxel: GC (Cohort C1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8[51]	18[52]	9[53]	10[54]
Units: hours				
median (full range (min-max))				

Cycle 1 Day 1, n=8, 18, 9, 10, 6, 15	7.53 (7.47 to 8.00)	7.73 (6.00 to 8.42)	7.53 (7.50 to 8.05)	7.50 (3.50 to 8.08)
Cycle 2 Day 1, n=7, 17, 8, 8, 5, 13	7.50 (6.00 to 7.57)	7.58 (7.50 to 8.38)	7.60 (7.50 to 8.25)	7.57 (7.50 to 8.00)

Notes:

[51] - Only participants with available data were analyzed.

[52] - Only participants with available data were analyzed.

[53] - Only participants with available data were analyzed.

[54] - Only participants with available data were analyzed.

End point values	Phase 2: INCB001158 100 mg + Paclitaxel: EC (Cohort C2)	Phase 2: INCB001158 100 mg + Paclitaxel: OC (Cohort C3)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[55]	15[56]		
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1, n=8, 18, 9, 10, 6, 15	7.53 (7.50 to 7.67)	7.65 (5.73 to 8.15)		
Cycle 2 Day 1, n=7, 17, 8, 8, 5, 13	7.55 (7.50 to 7.67)	7.58 (7.48 to 8.25)		

Notes:

[55] - Only participants with available data were analyzed.

[56] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

up to 1385 days

Adverse event reporting additional description:

Any adverse events either reported for the first time or the worsening of pre-existing events after the first dose of study drug have been reported. Data analysis was conducted based on treatment group and dose level, regardless of study phase, because the safety profile was expected to be generally uniform across tumor types.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Phase 1 and Phase 2: INCB001158 50 mg + mFOLFOX6

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 mg BID starting on Day 1 of each 28-day cycle. In Phases 1 and 2, participants with advanced or metastatic solid tumors (Phase 1) and MSS-CRC (Phase 2) also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Reporting group title	Phase 1 and Phase 2: INCB001158 75 mg + mFOLFOX6

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. In Phases 1 and 2, participants with advanced or solid metastatic tumors (Phase 1) and MSS-CRC (Phase 2) also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Reporting group title	Phase 1 and Phase 2: INCB001158 100 mg + mFOLFOX6

Reporting group description:

In Phases 1 and 2, participants with advanced or metastatic solid tumors (Phase 1) and MSS-CRC (Phase 2) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous mFOLFOX6 (oxaliplatin 85 mg/m^2, leucovorin 400 mg/m^2, and 5-fluorouracil 400 mg/m^2 [bolus] and 2400 mg/m^2 [continuous infusion]) on Day 1 and Day 15 of each 28-day cycle after administration of INCB001158.

Reporting group title	Phase 1 and Phase 2: INCB001158 50 mg+Gemcitabine+Cisplatin

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle. In Phase 2, participants with BTC received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 25 mg/m^2 on Day 1 and 8 of each 28-day cycle, and participants with OC received intravenous gemcitabine 750 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Reporting group title	Phase 1 and Phase 2: INCB001158 75 mg+Gemcitabine+Cisplatin

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. Participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle. In Phase 2, participants with BTC received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 25 mg/m^2 on Day 1 and 8 of each 28-day cycle, and participants with OC received intravenous gemcitabine 750 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Reporting group title	Phase 1 and Phase 2: INCB001158 100 mg+Gemcitabine+Cisplatin

Reporting group description:

In Phases 1 and 2, participants with advanced or metastatic solid tumors (Phase 1) and with BTC or OC

(Phase 2) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. In Phase 1, participants also received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and Day 8 of each 28-day cycle. In Phase 2, participants with BTC received intravenous gemcitabine 1000 mg/m^2 and intravenous cisplatin 25 mg/m^2 on Day 1 and 8 of each 28-day cycle, and participants with OC received intravenous gemcitabine 750 mg/m^2 and intravenous cisplatin 30 mg/m^2 on Day 1 and 8 of each 28-day cycle.

Reporting group title	Phase 1 and Phase 2: INCB001158 50 mg + Paclitaxel

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 50 mg BID starting on Day 1 of each 28-day cycle. In Phases 1 and 2, participants with advanced or metastatic solid tumors (Phase 1) and with GC, EC, or OC (Phase 2) received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Phase 1 and Phase 2: INCB001158 75 mg + Paclitaxel

Reporting group description:

In Phase 1, participants with advanced or metastatic solid tumors received oral INCB001158 75 mg BID starting on Day 1 of each 28-day cycle. In Phases 1 and 2, participants with advanced or metastatic solid tumors (Phase 1) and with GC, EC, or OC (Phase 2) received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Phase 1 and Phase 2: INCB001158 100 mg + Paclitaxel

Reporting group description:

In Phases 1 and 2, participants with advanced or metastatic solid tumors (Phase 1) and GC, EC, or OC (Phase 2) received oral INCB001158 100 mg BID starting on Day 1 of each 28-day cycle. Participants with advanced or metastatic solid tumors (Phase 1) and with GC, EC, or OC (Phase 2) also received intravenous paclitaxel 80 mg/m^2 on Day 1, Day 8, and Day 15 of each 28-day cycle.

Reporting group title	Total

Reporting group description:

Total

Serious adverse events	Phase 1 and Phase 2: INCB001158 50 mg + mFOLFOX6	Phase 1 and Phase 2: INCB001158 75 mg + mFOLFOX6	Phase 1 and Phase 2: INCB001158 100 mg + mFOLFOX6
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 8 (75.00%)	1 / 6 (16.67%)	7 / 14 (50.00%)
number of deaths (all causes)	4	2	11
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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			
Device related thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
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	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (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
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Assisted suicide			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (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
Mental status changes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (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
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Headache			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (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
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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			
Febrile neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 distension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (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

Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			

subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 intestine perforation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	2 / 8 (25.00%)	0 / 6 (0.00%)	0 / 14 (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
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
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 haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (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
Hyperbilirubinaemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (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
Septic shock			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (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
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (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
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (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
Hypomagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
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	Phase 1 and Phase 2: INCB001158 50 mg+Gemcitabine+Cisplatin	Phase 1 and Phase 2: INCB001158 75 mg+Gemcitabine+Cisplatin	Phase 1 and Phase 2: INCB001158 100 mg+Gemcitabine+Cisplatin
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 7 (42.86%)	1 / 4 (25.00%)	30 / 46 (65.22%)
number of deaths (all causes)	4	3	30
number of deaths resulting from adverse events	0	0	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
General disorders and administration site conditions			
Device related thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	5 / 46 (10.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
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, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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	1 / 7 (14.29%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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			
Assisted suicide			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
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			
Blood bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
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 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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			
Ankle fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
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 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	5 / 46 (10.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 46 (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
Colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 intestine perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	5 / 46 (10.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
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 perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	7 / 46 (15.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
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 and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
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 retention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 46 (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
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
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 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
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 candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
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 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 1 and Phase 2: INCB001158 50 mg + Paclitaxel	Phase 1 and Phase 2: INCB001158 75 mg + Paclitaxel	Phase 1 and Phase 2: INCB001158 100 mg + Paclitaxel
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 7 (57.14%)	4 / 5 (80.00%)	27 / 52 (51.92%)
number of deaths (all causes)	5	4	36
number of deaths resulting from adverse events	0	2	4
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 52 (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
Malignant ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			

subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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			
Device related thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	2 / 52 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 / 7 (14.29%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
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 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	4 / 52 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Assisted suicide			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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			
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 distension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 52 (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
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	3 / 7 (42.86%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
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 haemorrhage			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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	1 / 7 (14.29%)	1 / 5 (20.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
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 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
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 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 retention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
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 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
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 candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
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 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
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 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Urinary tract infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 52 (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
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Total		
Total subjects affected by serious adverse events			
subjects affected / exposed	83 / 149 (55.70%)		
number of deaths (all causes)	99		
number of deaths resulting from adverse events	11		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Malignant ascites			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tumour pain			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematoma			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
General disorders and administration site conditions			
Device related thrombosis			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Non-cardiac chest pain			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	9 / 149 (6.04%)		
occurrences causally related to treatment / all	1 / 11		
deaths causally related to treatment / all	0 / 0		

Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Female genital tract fistula			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	3 / 149 (2.01%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Pleural effusion			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 2		
Pneumonitis			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	6 / 149 (4.03%)		
occurrences causally related to treatment / all	2 / 6		
deaths causally related to treatment / all	0 / 1		
Respiratory failure			

subjects affected / exposed	2 / 149 (1.34%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Psychiatric disorders			
Assisted suicide			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Confusional state			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood bilirubin increased			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood creatinine increased			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular access complication			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Supraventricular tachycardia			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Brain oedema			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Headache			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Haemorrhage intracranial			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Leukocytosis			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	9 / 149 (6.04%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Abdominal pain lower				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	7 / 149 (4.70%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Duodenal obstruction				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	3 / 149 (2.01%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	3 / 149 (2.01%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				

subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	3 / 149 (2.01%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	7 / 149 (4.70%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Oesophagitis				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Small intestinal perforation				

subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	12 / 149 (8.05%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Biliary obstruction				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bile duct stone				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholangitis				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hepatic haemorrhage				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Jaundice cholestatic				

subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Jaundice			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Portal vein thrombosis			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Nephritis			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ureteric obstruction			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Back pain				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Infections and infestations				
Bacteraemia				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
COVID-19 pneumonia				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	4 / 149 (2.68%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection viral				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oesophageal candidiasis				

subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neutropenic sepsis				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oropharyngeal candidiasis				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	4 / 149 (2.68%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	4 / 149 (2.68%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Urinary tract infection				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urosepsis				

subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Wound infection				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Decreased appetite				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	6 / 149 (4.03%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Electrolyte imbalance				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	3 / 149 (2.01%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Hypernatraemia				

subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	3 / 149 (2.01%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hypomagnesaemia			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Phase 1 and Phase 2: INCB001158 50 mg + mFOLFOX6	Phase 1 and Phase 2: INCB001158 75 mg + mFOLFOX6	Phase 1 and Phase 2: INCB001158 100 mg + mFOLFOX6
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	6 / 6 (100.00%)	13 / 14 (92.86%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Tumour haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	3 / 8 (37.50%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	4	1	2
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Embolism			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	1	1	0

Haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	2
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	3
Lymphoedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Catheter site erythema			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	3 / 8 (37.50%)	4 / 6 (66.67%)	4 / 14 (28.57%)
occurrences (all)	5	4	5
General physical health deterioration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Infusion site extravasation			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Mucosal ulceration			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	2
Oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 8 (37.50%)	0 / 6 (0.00%)	3 / 14 (21.43%)
occurrences (all)	3	0	3
Swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Immune system disorders			

Hypersensitivity			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Reproductive system and breast disorders			
Intermenstrual bleeding			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 8 (37.50%)	1 / 6 (16.67%)	3 / 14 (21.43%)
occurrences (all)	3	2	3
Dyspnoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Dysphonia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Hiccups			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Pneumonitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pulmonary embolism			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Delirium			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Ammonia increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	2	2	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	4 / 14 (28.57%)
occurrences (all)	1	1	4
Blood cholesterol increased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Blood magnesium decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	2	1	1
Blood potassium decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Lipase increased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	1	3	2
Neutrophil count decreased			

subjects affected / exposed	4 / 8 (50.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	5	1	0
Platelet count decreased			
subjects affected / exposed	1 / 8 (12.50%)	3 / 6 (50.00%)	2 / 14 (14.29%)
occurrences (all)	1	4	4
Weight decreased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	3 / 14 (21.43%)
occurrences (all)	0	1	3
White blood cell count decreased			
subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	4	1	0
Weight increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Infusion related reaction			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	1	3	1
Procedural haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Skin laceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Stoma site erythema			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Wound dehiscence			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Cardiac disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Nervous system disorders			
Autonomic neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Balance disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	2	1	2
Dysaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dysgeusia			

subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	0	1	2
Hypoaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	0	1	2
Paraesthesia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	3 / 6 (50.00%)	4 / 14 (28.57%)
occurrences (all)	0	4	4
Somnolence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Taste disorder			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 8 (50.00%)	2 / 6 (33.33%)	2 / 14 (14.29%)
occurrences (all)	4	2	2
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Leukopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	5 / 14 (35.71%)
occurrences (all)	2	1	5
Normocytic anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Eye disorders			
Foreign body sensation in eyes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Glaucoma			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Retinopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	5 / 14 (35.71%)
occurrences (all)	2	1	7
Abdominal pain lower			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	0	1	2
Ascites			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Cheilitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	2	3	2
Diarrhoea			
subjects affected / exposed	3 / 8 (37.50%)	3 / 6 (50.00%)	6 / 14 (42.86%)
occurrences (all)	6	4	7
Dry mouth			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0

Faeces soft			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Gastrointestinal disorder			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Glossodynia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	5 / 8 (62.50%)	3 / 6 (50.00%)	5 / 14 (35.71%)
occurrences (all)	7	6	5
Oesophagitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Proctalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Rectal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	3 / 14 (21.43%)
occurrences (all)	0	2	3

Vomiting			
subjects affected / exposed	3 / 8 (37.50%)	1 / 6 (16.67%)	3 / 14 (21.43%)
occurrences (all)	3	1	3
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Drug eruption			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Nail disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Rash			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Renal failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Back pain			
subjects affected / exposed	3 / 8 (37.50%)	2 / 6 (33.33%)	1 / 14 (7.14%)
occurrences (all)	4	2	2
Groin pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Limb discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Muscular weakness			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Osteonecrosis of jaw			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Sacral pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Infections and infestations			
Biliary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Enterocolitis infectious			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0

Gastroenteritis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Lip infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Peritonitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Skin infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	0	1	3
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Viral upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 8 (37.50%)	2 / 6 (33.33%)	4 / 14 (28.57%)
occurrences (all)	3	2	4
Dehydration			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	2
Food intolerance			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	7	0	1
Hypernatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Hypoalbuminaemia			

subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 14 (7.14%)
occurrences (all)	2	2	1
Hypocalcaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Hypoglycaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Hypokalaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	2 / 14 (14.29%)
occurrences (all)	2	0	3
Hypomagnesaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	2 / 14 (14.29%)
occurrences (all)	1	1	3
Hypophosphataemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Non-serious adverse events	Phase 1 and Phase 2: INCB001158 50 mg+Gemcitabine+Cisplatin	Phase 1 and Phase 2: INCB001158 75 mg+Gemcitabine+Cisplatin	Phase 1 and Phase 2: INCB001158 100 mg+Gemcitabine+Cisplatin
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	4 / 4 (100.00%)	45 / 46 (97.83%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Tumour pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	4 / 46 (8.70%)
occurrences (all)	0	0	4
Embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Lymphoedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Catheter site erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	4 / 46 (8.70%)
occurrences (all)	0	0	5
Fatigue			

subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	23 / 46 (50.00%)
occurrences (all)	1	1	33
General physical health deterioration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	1	0	2
Infusion site extravasation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Mucosal ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 7 (28.57%)	0 / 4 (0.00%)	9 / 46 (19.57%)
occurrences (all)	2	0	10
Oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	2
Peripheral swelling			

subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	4 / 46 (8.70%)
occurrences (all)	1	0	5
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	9 / 46 (19.57%)
occurrences (all)	0	0	11
Swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Intermenstrual bleeding			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	9 / 46 (19.57%)
occurrences (all)	0	1	9
Dyspnoea			
subjects affected / exposed	2 / 7 (28.57%)	1 / 4 (25.00%)	8 / 46 (17.39%)
occurrences (all)	2	1	9
Dysphonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	2 / 46 (4.35%)
occurrences (all)	0	1	3
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	3
Hiccups			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Rhinitis allergic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Delirium			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0

Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	8 / 46 (17.39%)
occurrences (all)	0	0	8
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	9 / 46 (19.57%)
occurrences (all)	1	1	18
Ammonia increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	1 / 46 (2.17%)
occurrences (all)	0	2	1
Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 7 (42.86%)	0 / 4 (0.00%)	9 / 46 (19.57%)
occurrences (all)	3	0	14
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	1	0	4
Blood cholesterol increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	13 / 46 (28.26%)
occurrences (all)	0	1	18
Blood potassium decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	3 / 7 (42.86%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	5	0	5
Neutrophil count decreased			
subjects affected / exposed	4 / 7 (57.14%)	0 / 4 (0.00%)	15 / 46 (32.61%)
occurrences (all)	5	0	31
Platelet count decreased			
subjects affected / exposed	5 / 7 (71.43%)	0 / 4 (0.00%)	14 / 46 (30.43%)
occurrences (all)	9	0	29
Weight decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	2
White blood cell count decreased			
subjects affected / exposed	5 / 7 (71.43%)	1 / 4 (25.00%)	8 / 46 (17.39%)
occurrences (all)	6	1	13
Weight increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Procedural haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Procedural pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Stoma site erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Wound dehiscence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Cardiac disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Supraventricular extrasystoles			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Nervous system disorders			
Autonomic neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	11 / 46 (23.91%)
occurrences (all)	0	0	13
Dysaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	3 / 46 (6.52%)
occurrences (all)	0	1	3
Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	10 / 46 (21.74%)
occurrences (all)	0	0	14
Hypoaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	2 / 46 (4.35%)
occurrences (all)	0	1	2
Neuropathy peripheral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	6 / 46 (13.04%)
occurrences (all)	0	0	7
Paraesthesia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	1	0	2
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	6 / 46 (13.04%)
occurrences (all)	0	1	7
Somnolence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	5 / 7 (71.43%)	2 / 4 (50.00%)	25 / 46 (54.35%)
occurrences (all)	5	2	38
Leukocytosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	2
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	11 / 46 (23.91%)
occurrences (all)	1	1	25
Normocytic anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	10 / 46 (21.74%)
occurrences (all)	1	2	16
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	5 / 46 (10.87%)
occurrences (all)	1	0	5
Eye disorders			
Foreign body sensation in eyes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Retinopathy			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Vision blurred			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Vitreous floaters			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	2
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	2
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	5 / 46 (10.87%)
occurrences (all)	0	0	5
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	9 / 46 (19.57%)
occurrences (all)	1	1	18
Abdominal pain lower			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	2
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	4 / 46 (8.70%)
occurrences (all)	0	0	4
Ascites			
subjects affected / exposed	3 / 7 (42.86%)	0 / 4 (0.00%)	4 / 46 (8.70%)
occurrences (all)	3	0	5
Cheilitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	2 / 4 (50.00%)	19 / 46 (41.30%)
occurrences (all)	0	2	29
Diarrhoea			
subjects affected / exposed	2 / 7 (28.57%)	0 / 4 (0.00%)	11 / 46 (23.91%)
occurrences (all)	4	0	17
Dry mouth			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	0 / 46 (0.00%)
occurrences (all)	0	1	0

Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	5 / 46 (10.87%)
occurrences (all)	0	0	6
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Faeces soft			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	3 / 46 (6.52%)
occurrences (all)	0	1	3
Glossodynia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	25 / 46 (54.35%)
occurrences (all)	1	1	44
Oesophagitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0

Retching			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	6 / 46 (13.04%)
occurrences (all)	0	0	6
Vomiting			
subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	14 / 46 (30.43%)
occurrences (all)	1	1	26
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	2 / 46 (4.35%)
occurrences (all)	0	1	2
Dermatitis acneiform			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	5
Rash maculo-papular			

subjects affected / exposed	0 / 7 (0.00%)	2 / 4 (50.00%)	2 / 46 (4.35%)
occurrences (all)	0	2	2
Rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	5 / 46 (10.87%)
occurrences (all)	0	0	5
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	2
Dysuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	2
Haematuria			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	1	0	1
Proteinuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	0 / 46 (0.00%)
occurrences (all)	0	2	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	0 / 46 (0.00%)
occurrences (all)	0	2	0
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 4 (0.00%)	8 / 46 (17.39%)
occurrences (all)	2	0	10
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	9 / 46 (19.57%)
occurrences (all)	0	0	14
Groin pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	1	0	1
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	3
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	7 / 46 (15.22%)
occurrences (all)	0	0	9
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Osteonecrosis of jaw			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Sacral pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Biliary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0

Ear infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Enterocolitis infectious			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	3
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Peritonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Skin infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	1	0	1

Upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	5 / 46 (10.87%)
occurrences (all)	1	0	5
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	6 / 46 (13.04%)
occurrences (all)	0	0	7
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 7 (28.57%)	1 / 4 (25.00%)	12 / 46 (26.09%)
occurrences (all)	2	1	14
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	4
Food intolerance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	3 / 7 (42.86%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	4	0	3
Hypernatraemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	1	0	3
Hypertriglyceridaemia			

subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	1 / 46 (2.17%)
occurrences (all)	2	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Hypoalbuminaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	5 / 46 (10.87%)
occurrences (all)	3	0	5
Hypocalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	7 / 46 (15.22%)
occurrences (all)	0	0	7
Hypoglycaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	6 / 46 (13.04%)
occurrences (all)	0	0	6
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	5 / 46 (10.87%)
occurrences (all)	0	1	8
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	2
Vitamin D deficiency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1 and Phase 2: INCB001158 50 mg + Paclitaxel	Phase 1 and Phase 2: INCB001158 75 mg + Paclitaxel	Phase 1 and Phase 2: INCB001158 100 mg + Paclitaxel
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	5 / 5 (100.00%)	50 / 52 (96.15%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Seborrhoeic keratosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	1	0	3
Embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	8 / 52 (15.38%)
occurrences (all)	1	0	12
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	4 / 52 (7.69%)
occurrences (all)	0	0	4
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Lymphoedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	3
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Catheter site erythema			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	5
Fatigue			
subjects affected / exposed	2 / 7 (28.57%)	4 / 5 (80.00%)	29 / 52 (55.77%)
occurrences (all)	2	5	38
General physical health deterioration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	4 / 52 (7.69%)
occurrences (all)	0	0	5
Infusion site extravasation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Localised oedema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	4
Mucosal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	4 / 52 (7.69%)
occurrences (all)	0	0	4
Mucosal ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 7 (14.29%)	1 / 5 (20.00%)	13 / 52 (25.00%)
occurrences (all)	1	1	20
Oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 7 (0.00%)	2 / 5 (40.00%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
Peripheral swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 5 (40.00%)	6 / 52 (11.54%)
occurrences (all)	0	2	8
Swelling			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Intermenstrual bleeding			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 7 (0.00%)	2 / 5 (40.00%)	8 / 52 (15.38%)
occurrences (all)	0	2	10
Dyspnoea			
subjects affected / exposed	4 / 7 (57.14%)	0 / 5 (0.00%)	7 / 52 (13.46%)
occurrences (all)	4	0	12
Dysphonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	4
Dyspnoea exertional			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	4 / 52 (7.69%)
occurrences (all)	0	0	5
Hiccups			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	5 / 52 (9.62%)
occurrences (all)	1	0	5
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Rhinitis allergic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	4
Rhinorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Wheezing			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	2
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	5 / 52 (9.62%)
occurrences (all)	0	0	6

Confusional state			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	5 / 52 (9.62%)
occurrences (all)	0	1	5
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Ammonia increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	8
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	4
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	6 / 52 (11.54%)
occurrences (all)	0	0	6
Blood cholesterol increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	8 / 52 (15.38%)
occurrences (all)	0	0	9
Blood potassium decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	7
Lipase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	6
Neutrophil count decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	9 / 52 (17.31%)
occurrences (all)	0	1	19
Platelet count decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	3 / 52 (5.77%)
occurrences (all)	0	1	6
Weight decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	5 / 52 (9.62%)
occurrences (all)	1	0	5
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	11 / 52 (21.15%)
occurrences (all)	0	0	28
Weight increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	4 / 52 (7.69%)
occurrences (all)	0	0	4
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Infusion related reaction			

subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Procedural haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Skin laceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Stoma site erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Wound dehiscence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Cardiac disorder			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Supraventricular extrasystoles			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	3
Nervous system disorders			
Autonomic neuropathy			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 7 (28.57%)	0 / 5 (0.00%)	10 / 52 (19.23%)
occurrences (all)	2	0	13
Dysaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	6 / 52 (11.54%)
occurrences (all)	0	0	12
Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	9 / 52 (17.31%)
occurrences (all)	0	0	9
Hypoaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	3 / 7 (42.86%)	0 / 5 (0.00%)	10 / 52 (19.23%)
occurrences (all)	3	0	12
Paraesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	5 / 52 (9.62%)
occurrences (all)	0	0	5
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 7 (14.29%)	2 / 5 (40.00%)	10 / 52 (19.23%)
occurrences (all)	1	2	11
Somnolence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	4 / 52 (7.69%)
occurrences (all)	1	0	4
Taste disorder			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Tremor			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 7 (28.57%)	1 / 5 (20.00%)	21 / 52 (40.38%)
occurrences (all)	3	2	30
Leukocytosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	4
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	4
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	7 / 52 (13.46%)
occurrences (all)	0	0	17
Normocytic anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Eye disorders			
Foreign body sensation in eyes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Glaucoma			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Retinopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Vitreous floaters			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Abdominal distension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	8 / 52 (15.38%)
occurrences (all)	1	0	11
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	15 / 52 (28.85%)
occurrences (all)	1	0	19
Abdominal pain lower			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	3
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	5 / 52 (9.62%)
occurrences (all)	0	0	8
Ascites			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	4 / 52 (7.69%)
occurrences (all)	2	0	7
Cheilitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	4 / 52 (7.69%)
occurrences (all)	0	0	4
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	1 / 5 (20.00%)	13 / 52 (25.00%)
occurrences (all)	1	1	13

Diarrhoea			
subjects affected / exposed	3 / 7 (42.86%)	1 / 5 (20.00%)	16 / 52 (30.77%)
occurrences (all)	3	1	25
Dry mouth			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	1	0	1
Dyspepsia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	1	0	2
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	3
Faeces soft			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	4 / 52 (7.69%)
occurrences (all)	0	0	4
Glossodynia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 7 (42.86%)	3 / 5 (60.00%)	21 / 52 (40.38%)
occurrences (all)	4	3	43
Oesophagitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0

Proctalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	1	0	1
Retching			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	10 / 52 (19.23%)
occurrences (all)	0	0	12
Vomiting			
subjects affected / exposed	1 / 7 (14.29%)	3 / 5 (60.00%)	18 / 52 (34.62%)
occurrences (all)	2	6	29
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 5 (40.00%)	18 / 52 (34.62%)
occurrences (all)	1	2	20
Dermatitis acneiform			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	3
Hyperhidrosis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	1	0	5
Nail disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	5 / 52 (9.62%)
occurrences (all)	0	0	6
Photosensitivity reaction			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	6 / 52 (11.54%)
occurrences (all)	0	1	8
Rash maculo-papular			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	6 / 52 (11.54%)
occurrences (all)	1	0	9
Rash			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	7 / 52 (13.46%)
occurrences (all)	0	1	7
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	2
Dysuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	4
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	3
Proteinuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	6 / 52 (11.54%)
occurrences (all)	0	0	7
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	11 / 52 (21.15%)
occurrences (all)	0	1	13
Back pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	9 / 52 (17.31%)
occurrences (all)	1	0	10
Groin pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Limb discomfort			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	7 / 52 (13.46%)
occurrences (all)	0	0	9
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	6
Muscle spasms			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	5 / 52 (9.62%)
occurrences (all)	1	0	6
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	1 / 52 (1.92%)
occurrences (all)	0	2	1
Osteonecrosis of jaw			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	2 / 5 (40.00%)	4 / 52 (7.69%)
occurrences (all)	0	2	4
Sacral pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Biliary tract infection			

subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Enterocolitis infectious			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	1	0	1
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	3
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Peritonitis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 5 (20.00%)	1 / 52 (1.92%)
occurrences (all)	0	1	1
Skin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	7 / 52 (13.46%)
occurrences (all)	1	0	9
Urinary tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	6 / 52 (11.54%)
occurrences (all)	1	0	15
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 7 (28.57%)	1 / 5 (20.00%)	10 / 52 (19.23%)
occurrences (all)	2	1	16
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	9 / 52 (17.31%)
occurrences (all)	0	0	10
Food intolerance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	5 / 52 (9.62%)
occurrences (all)	0	0	8

Hypernatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	1	0	5
Hypertriglyceridaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	3
Hyperuricaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	2	0	3
Hypocalcaemia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 5 (0.00%)	2 / 52 (3.85%)
occurrences (all)	3	0	2
Hypoglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	8 / 52 (15.38%)
occurrences (all)	2	0	12
Hypomagnesaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	3 / 52 (5.77%)
occurrences (all)	1	0	3
Hyponatraemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 5 (0.00%)	5 / 52 (9.62%)
occurrences (all)	2	0	9
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	5 / 52 (9.62%)
occurrences (all)	0	0	5
Vitamin D deficiency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 5 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1

Non-serious adverse events	Total		
Total subjects affected by non-serious adverse events subjects affected / exposed	145 / 149 (97.32%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Seborrhoeic keratosis subjects affected / exposed occurrences (all) Tumour haemorrhage subjects affected / exposed occurrences (all) Tumour pain subjects affected / exposed occurrences (all)	 1 / 149 (0.67%) 1 1 / 149 (0.67%) 1 6 / 149 (4.03%) 8		
Vascular disorders Deep vein thrombosis subjects affected / exposed occurrences (all) Embolism subjects affected / exposed occurrences (all) Haematoma subjects affected / exposed occurrences (all) Hot flush subjects affected / exposed occurrences (all) Hypertension subjects affected / exposed occurrences (all) Hypotension subjects affected / exposed occurrences (all) Lymphoedema subjects affected / exposed occurrences (all)	 10 / 149 (6.71%) 10 3 / 149 (2.01%) 3 2 / 149 (1.34%) 2 9 / 149 (6.04%) 13 8 / 149 (5.37%) 8 5 / 149 (3.36%) 6 3 / 149 (2.01%) 3		
General disorders and administration			

site conditions				
Asthenia				
subjects affected / exposed	3 / 149 (2.01%)			
occurrences (all)	4			
Catheter site erythema				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Chills				
subjects affected / exposed	8 / 149 (5.37%)			
occurrences (all)	11			
Fatigue				
subjects affected / exposed	71 / 149 (47.65%)			
occurrences (all)	94			
General physical health deterioration				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Influenza like illness				
subjects affected / exposed	8 / 149 (5.37%)			
occurrences (all)	9			
Infusion site extravasation				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Localised oedema				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Malaise				
subjects affected / exposed	4 / 149 (2.68%)			
occurrences (all)	5			
Mucosal inflammation				
subjects affected / exposed	5 / 149 (3.36%)			
occurrences (all)	5			
Mucosal ulceration				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Oedema peripheral				

subjects affected / exposed	29 / 149 (19.46%)		
occurrences (all)	38		
Oedema			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Non-cardiac chest pain			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	5		
Pain			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences (all)	4		
Peripheral swelling			
subjects affected / exposed	6 / 149 (4.03%)		
occurrences (all)	7		
Pyrexia			
subjects affected / exposed	23 / 149 (15.44%)		
occurrences (all)	27		
Swelling			
subjects affected / exposed	3 / 149 (2.01%)		
occurrences (all)	3		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	3 / 149 (2.01%)		
occurrences (all)	3		
Reproductive system and breast disorders			
Intermenstrual bleeding			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Pelvic pain			
subjects affected / exposed	3 / 149 (2.01%)		
occurrences (all)	3		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	27 / 149 (18.12%)		
occurrences (all)	30		
Dyspnoea			

subjects affected / exposed	23 / 149 (15.44%)			
occurrences (all)	29			
Dysphonia				
subjects affected / exposed	4 / 149 (2.68%)			
occurrences (all)	5			
Dyspnoea exertional				
subjects affected / exposed	3 / 149 (2.01%)			
occurrences (all)	4			
Epistaxis				
subjects affected / exposed	7 / 149 (4.70%)			
occurrences (all)	10			
Hiccups				
subjects affected / exposed	5 / 149 (3.36%)			
occurrences (all)	5			
Hypoxia				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences (all)	2			
Oropharyngeal pain				
subjects affected / exposed	9 / 149 (6.04%)			
occurrences (all)	10			
Pneumonitis				
subjects affected / exposed	3 / 149 (2.01%)			
occurrences (all)	3			
Pleural effusion				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences (all)	2			
Pulmonary embolism				
subjects affected / exposed	7 / 149 (4.70%)			
occurrences (all)	7			
Rhinitis allergic				
subjects affected / exposed	3 / 149 (2.01%)			
occurrences (all)	4			
Rhinorrhoea				
subjects affected / exposed	3 / 149 (2.01%)			
occurrences (all)	3			
Wheezing				

subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	3		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	7 / 149 (4.70%)		
occurrences (all)	8		
Confusional state			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Delirium			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	15 / 149 (10.07%)		
occurrences (all)	16		
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Alanine aminotransferase increased			
subjects affected / exposed	14 / 149 (9.40%)		
occurrences (all)	24		
Ammonia increased			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	3		
Amylase increased			
subjects affected / exposed	7 / 149 (4.70%)		
occurrences (all)	13		
Aspartate aminotransferase increased			
subjects affected / exposed	16 / 149 (10.74%)		
occurrences (all)	22		
Blood alkaline phosphatase increased			
subjects affected / exposed	16 / 149 (10.74%)		
occurrences (all)	17		
Blood cholesterol increased			

subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Blood magnesium decreased			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Blood creatinine increased			
subjects affected / exposed	26 / 149 (17.45%)		
occurrences (all)	32		
Blood potassium decreased			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Blood thyroid stimulating hormone increased			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences (all)	8		
Lipase increased			
subjects affected / exposed	12 / 149 (8.05%)		
occurrences (all)	22		
Neutrophil count decreased			
subjects affected / exposed	34 / 149 (22.82%)		
occurrences (all)	62		
Platelet count decreased			
subjects affected / exposed	29 / 149 (19.46%)		
occurrences (all)	54		
Weight decreased			
subjects affected / exposed	12 / 149 (8.05%)		
occurrences (all)	12		
White blood cell count decreased			
subjects affected / exposed	28 / 149 (18.79%)		
occurrences (all)	53		
Weight increased			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences (all)	4		
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	5		
Fall			
subjects affected / exposed	3 / 149 (2.01%)		
occurrences (all)	4		
Infusion related reaction			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	7		
Procedural haemorrhage			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Procedural pain			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Skin laceration			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	3		
Stoma site erythema			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Wound dehiscence			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Cardiac disorders			
Bradycardia			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Cardiac disorder			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Palpitations			
subjects affected / exposed	3 / 149 (2.01%)		
occurrences (all)	3		
Supraventricular extrasystoles			

subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	5		
Nervous system disorders			
Autonomic neuropathy			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Balance disorder			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	27 / 149 (18.12%)		
occurrences (all)	33		
Dysaesthesia			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Dysgeusia			
subjects affected / exposed	11 / 149 (7.38%)		
occurrences (all)	17		
Headache			
subjects affected / exposed	22 / 149 (14.77%)		
occurrences (all)	26		
Hypoaesthesia			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences (all)	4		
Neuropathy peripheral			
subjects affected / exposed	22 / 149 (14.77%)		
occurrences (all)	25		
Paraesthesia			
subjects affected / exposed	9 / 149 (6.04%)		
occurrences (all)	9		
Peripheral sensory neuropathy			
subjects affected / exposed	27 / 149 (18.12%)		
occurrences (all)	30		

Somnolence			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Syncope			
subjects affected / exposed	6 / 149 (4.03%)		
occurrences (all)	7		
Taste disorder			
subjects affected / exposed	3 / 149 (2.01%)		
occurrences (all)	3		
Tremor			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	64 / 149 (42.95%)		
occurrences (all)	88		
Leukocytosis			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	6		
Leukopenia			
subjects affected / exposed	3 / 149 (2.01%)		
occurrences (all)	5		
Neutropenia			
subjects affected / exposed	28 / 149 (18.79%)		
occurrences (all)	52		
Normocytic anaemia			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Thrombocytopenia			
subjects affected / exposed	15 / 149 (10.07%)		
occurrences (all)	22		
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Tinnitus			

subjects affected / exposed	10 / 149 (6.71%)		
occurrences (all)	10		
Eye disorders			
Foreign body sensation in eyes			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Glaucoma			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Retinopathy			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Vision blurred			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences (all)	4		
Vitreous floaters			
subjects affected / exposed	3 / 149 (2.01%)		
occurrences (all)	4		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	5		
Abdominal distension			
subjects affected / exposed	14 / 149 (9.40%)		
occurrences (all)	17		
Abdominal pain			
subjects affected / exposed	35 / 149 (23.49%)		
occurrences (all)	50		
Abdominal pain lower			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	5		
Abdominal pain upper			
subjects affected / exposed	12 / 149 (8.05%)		
occurrences (all)	15		
Ascites			

subjects affected / exposed	13 / 149 (8.72%)			
occurrences (all)	18			
Cheilitis				
subjects affected / exposed	4 / 149 (2.68%)			
occurrences (all)	4			
Constipation				
subjects affected / exposed	41 / 149 (27.52%)			
occurrences (all)	53			
Diarrhoea				
subjects affected / exposed	45 / 149 (30.20%)			
occurrences (all)	67			
Dry mouth				
subjects affected / exposed	4 / 149 (2.68%)			
occurrences (all)	4			
Dyspepsia				
subjects affected / exposed	9 / 149 (6.04%)			
occurrences (all)	10			
Dysphagia				
subjects affected / exposed	5 / 149 (3.36%)			
occurrences (all)	5			
Faeces soft				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Gastrointestinal disorder				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	2			
Gastrooesophageal reflux disease				
subjects affected / exposed	9 / 149 (6.04%)			
occurrences (all)	9			
Glossodynia				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Haemorrhoids				
subjects affected / exposed	4 / 149 (2.68%)			
occurrences (all)	4			
Lower gastrointestinal haemorrhage				

subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	67 / 149 (44.97%)		
occurrences (all)	114		
Oesophagitis			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Proctalgia			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Rectal haemorrhage			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Retching			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Stomatitis			
subjects affected / exposed	21 / 149 (14.09%)		
occurrences (all)	23		
Vomiting			
subjects affected / exposed	45 / 149 (30.20%)		
occurrences (all)	72		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	24 / 149 (16.11%)		
occurrences (all)	26		
Dermatitis acneiform			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Drug eruption			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Dry skin			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences (all)	4		

Hyperhidrosis			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences (all)	7		
Nail disorder			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	6		
Photosensitivity reaction			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	10 / 149 (6.71%)		
occurrences (all)	14		
Rash maculo-papular			
subjects affected / exposed	12 / 149 (8.05%)		
occurrences (all)	16		
Rash			
subjects affected / exposed	14 / 149 (9.40%)		
occurrences (all)	14		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences (all)	5		
Dysuria			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	6		
Haematuria			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	6		
Proteinuria			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Renal failure			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	2		
Endocrine disorders			

Hyperthyroidism			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	3		
Hypothyroidism			
subjects affected / exposed	6 / 149 (4.03%)		
occurrences (all)	7		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	24 / 149 (16.11%)		
occurrences (all)	28		
Back pain			
subjects affected / exposed	25 / 149 (16.78%)		
occurrences (all)	33		
Groin pain			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Limb discomfort			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Myalgia			
subjects affected / exposed	12 / 149 (8.05%)		
occurrences (all)	14		
Muscular weakness			
subjects affected / exposed	6 / 149 (4.03%)		
occurrences (all)	10		
Muscle spasms			
subjects affected / exposed	14 / 149 (9.40%)		
occurrences (all)	17		
Neck pain			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences (all)	5		
Osteonecrosis of jaw			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Pain in extremity			

subjects affected / exposed	10 / 149 (6.71%)		
occurrences (all)	10		
Sacral pain			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Infections and infestations			
Biliary tract infection			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Cellulitis			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences (all)	4		
Conjunctivitis			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Ear infection			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Enterocolitis infectious			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Herpes zoster			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Infection			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Lip infection			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Lower respiratory tract infection			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	6		

Oral herpes			
subjects affected / exposed	3 / 149 (2.01%)		
occurrences (all)	3		
Oral candidiasis			
subjects affected / exposed	3 / 149 (2.01%)		
occurrences (all)	3		
Peritonitis			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Rhinitis			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	5		
Skin infection			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences (all)	4		
Upper respiratory tract infection			
subjects affected / exposed	17 / 149 (11.41%)		
occurrences (all)	20		
Urinary tract infection			
subjects affected / exposed	13 / 149 (8.72%)		
occurrences (all)	23		
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	37 / 149 (24.83%)		
occurrences (all)	45		
Dehydration			
subjects affected / exposed	14 / 149 (9.40%)		
occurrences (all)	18		
Food intolerance			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Hypercholesterolaemia			

subjects affected / exposed	2 / 149 (1.34%)			
occurrences (all)	2			
Hypercalcaemia				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Hyperglycaemia				
subjects affected / exposed	13 / 149 (8.72%)			
occurrences (all)	23			
Hypernatraemia				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences (all)	2			
Hyperkalaemia				
subjects affected / exposed	9 / 149 (6.04%)			
occurrences (all)	11			
Hypertriglyceridaemia				
subjects affected / exposed	6 / 149 (4.03%)			
occurrences (all)	9			
Hyperuricaemia				
subjects affected / exposed	6 / 149 (4.03%)			
occurrences (all)	6			
Hypoalbuminaemia				
subjects affected / exposed	14 / 149 (9.40%)			
occurrences (all)	18			
Hypocalcaemia				
subjects affected / exposed	13 / 149 (8.72%)			
occurrences (all)	15			
Hypoglycaemia				
subjects affected / exposed	3 / 149 (2.01%)			
occurrences (all)	3			
Hypokalaemia				
subjects affected / exposed	15 / 149 (10.07%)			
occurrences (all)	22			
Hypomagnesaemia				
subjects affected / exposed	11 / 149 (7.38%)			
occurrences (all)	11			
Hyponatraemia				

subjects affected / exposed	16 / 149 (10.74%)		
occurrences (all)	25		
Hypophosphataemia			
subjects affected / exposed	7 / 149 (4.70%)		
occurrences (all)	7		
Vitamin D deficiency			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 October 2017	The primary purpose of this amendment was to address changes requested by the Medicines & Healthcare products Regulatory Agency (MHRA) in the United Kingdom.
27 September 2018	The primary purpose of this amendment was to update the inclusion criteria for the microsatellite stable colorectal cancer (MSS-CRC) expansion cohort.
17 May 2019	The primary purpose of this amendment was to change the study drug formulation.
09 December 2020	The primary purpose of this amendment was to provide guidance for the management of ongoing participants, as enrollment was complete and sufficient data had been collected for primary and secondary endpoint analysis.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported