Clinical trial results:
A Phase I/II Open–Label, Three-Part, Dose-Finding and Separate Cohort Expansion Trial to Assess the Safety, Tolerability and Preliminary Efficacy of Repeated Doses of CLEVER-1 Antibody FP-1305, in Subjects with Advanced Solid Tumours

Summary

EudraCT number	2018-002732-24
Trial protocol	FI GB NL FR
Global end of trial date	31 October 2023

Results information

Result version number	v1 (current)
This version publication date	15 March 2025
First version publication date	15 March 2025

Trial information

Trial identification

Sponsor protocol code	FP2CLI001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03733990
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Faron Pharmaceuticals Ltd
Sponsor organisation address	Joukahaisenkatu 6, Turku, Finland, 20520
Public contact	Regulatory Affairs, Faron Pharmaceuticals, regulatory.affairs@faron.com
Scientific contact	Regulatory Affairs, Faron Pharmaceuticals, regulatory.affairs@faron.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	13 December 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 September 2023
Global end of trial reached?	Yes
Global end of trial date	31 October 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

• To determine the safety, tolerability and recommended dose of FP-1305 in subjects with advanced solid tumours of the selected tumour types without standard treatment options
• To determine the safety, tolerability and preliminary efficacy of FP-1305 monotherapy with the objective response rate (ORR), clinical benefit rate (CBR) and immune-related ORR (irORR) in distinct expansion groups of subjects with advanced solid tumours of the selected tumour types
• To assess the ORR, CBR and irORR in distinct expansion groups of subjects with advanced solid tumours in CLEVER-1 positive subjects from selected tumour types at a selected dose

Protection of trial subjects:

Various measures were in place for the protection of trial subjects, which include:

Safety assessments prior, during, and post-treatment as per protocol's schedule of events
Thorough adverse event reporting
Dose modifications
List of prohibited interventions (concomitant interventions)
Infusion delays
Hold of treatment in complete response
Management of Toxicities (section 8.9)
Contraceptive requirements for males and women of childbearing potential
Monitoring pregnancies for potential adverse events

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 31
Country: Number of subjects enrolled	Spain: 36
Country: Number of subjects enrolled	United Kingdom: 37
Country: Number of subjects enrolled	Finland: 72
Country: Number of subjects enrolled	France: 35
Country: Number of subjects enrolled	United States: 5
Worldwide total number of subjects	216
EEA total number of subjects	174

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)	139
From 65 to 84 years	77
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A signed informed consent is available before any screening procedures.
During the screening period, a subject's eligibility for the trial is determined by evaluation of the exclusion and inclusion criteria.
Subjects will undergo a medical history review with several parameters assessed (see section 6 of the protocol for more details)

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	FP-1305 (Bexmarilimab) 0.1 mg/kg

Arm description:

Part I Dose-escalation FP-1305 0.1 mg/kg is administered in Q3W intervals FP-1305 (bexmarilimab)

Arm type	Experimental
Investigational medicinal product name	Bexmarilimab
Investigational medicinal product code	FP-1305
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The dose was be dependent on treatment arm and was be calculated based on mg/ml, the dose will be administered either Q1W, Q2W, Q3W based on treatment arm and study part

Arm title	FP-1305 (Bexmarilimab) 0.3 mg/kg

Arm description:

Part I, Dose-escalation FP-1305 0.3 mg/kg is administered in Q3W intervals

Arm type	Experimental
Investigational medicinal product name	Bexmarilimab
Investigational medicinal product code	FP-1305
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The dose was be dependent on treatment arm and was be calculated based on mg/ml, the dose will be administered either Q1W, Q2W, Q3W based on treatment arm and study part

Arm title	FP-1305 (Bexmarilimab) 1 mg/kg

Arm description:

Part I and II, Dose-escalation FP-1305 1 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)

Arm type	Experimental

Investigational medicinal product name	Bexmarilimab
Investigational medicinal product code	FP-1305
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The dose was be dependent on treatment arm and was be calculated based on mg/ml, the dose will be administered either Q1W, Q2W, Q3W based on treatment arm and study part

Arm title	FP-1305 (Bexmarilimab) 3 mg/kg

Arm description:

Part I and II, Dose-escalation FP-1305 3 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)

Arm type	Experimental
Investigational medicinal product name	Bexmarilimab
Investigational medicinal product code	FP-1305
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The dose was be dependent on treatment arm and was be calculated based on mg/ml, the dose will be administered either Q1W, Q2W, Q3W based on treatment arm and study part

Arm title	FP-1305 (Bexmarilimab) 10 mg/kg

Arm description:

Part I and II, Dose-escalation FP-1305 10 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)

Arm type	Experimental
Investigational medicinal product name	Bexmarilimab
Investigational medicinal product code	FP-1305
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The dose was be dependent on treatment arm and was be calculated based on mg/ml, the dose will be administered either Q1W, Q2W, Q3W based on treatment arm and study part

Arm title	FP-1305 (Bexmarilimab) 30 mg/kg

Arm description:

Part II Dose-escalation FP-1305 30 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)

Arm type	Experimental
Investigational medicinal product name	Bexmarilimab
Investigational medicinal product code	FP-1305
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The dose was be dependent on treatment arm and was be calculated based on mg/ml, the dose will be administered either Q1W, Q2W, Q3W based on treatment arm and study part

Number of subjects in period 1	FP-1305 (Bexmarilimab) 0.1 mg/kg	FP-1305 (Bexmarilimab) 0.3 mg/kg	FP-1305 (Bexmarilimab) 1 mg/kg
Started	5	13	130
Completed	5	13	130

Number of subjects in period 1	FP-1305 (Bexmarilimab) 3 mg/kg	FP-1305 (Bexmarilimab) 10 mg/kg	FP-1305 (Bexmarilimab) 30 mg/kg
Started	41	18	9
Completed	41	18	9

Baseline characteristics

Reporting groups	
Reporting group title	FP-1305 (Bexmarilimab) 0.1 mg/kg
Reporting group description:	
Part I Dose-escalation FP-1305 0.1 mg/kg is administered in Q3W intervals FP-1305 (bexmarilimab)	
Reporting group title	FP-1305 (Bexmarilimab) 0.3 mg/kg
Reporting group description:	
Part I, Dose-escalation FP-1305 0.3 mg/kg is administered in Q3W intervals	
Reporting group title	FP-1305 (Bexmarilimab) 1 mg/kg
Reporting group description:	
Part I and II, Dose-escalation FP-1305 1 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)	
Reporting group title	FP-1305 (Bexmarilimab) 3 mg/kg
Reporting group description:	
Part I and II, Dose-escalation FP-1305 3 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)	
Reporting group title	FP-1305 (Bexmarilimab) 10 mg/kg
Reporting group description:	
Part I and II, Dose-escalation FP-1305 10 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)	
Reporting group title	FP-1305 (Bexmarilimab) 30 mg/kg
Reporting group description:	
Part II Dose-escalation FP-1305 30 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)	

Reporting group values	FP-1305 (Bexmarilimab) 0.1 mg/kg	FP-1305 (Bexmarilimab) 0.3 mg/kg	FP-1305 (Bexmarilimab) 1 mg/kg
Number of subjects	5	13	130
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	3	91
From 65-84 years	2	10	39
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	57.60	67.15	59.67
standard deviation	± 16.950	± 5.444	± 10.563
Gender categorical			
Units: Subjects			
Female	5	8	60
Male	0	5	70

Reporting group values	FP-1305 (Bexmarilimab) 3 mg/kg	FP-1305 (Bexmarilimab) 10 mg/kg	FP-1305 (Bexmarilimab) 30 mg/kg
Number of subjects	41	18	9
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	25	9	8
From 65-84 years	16	9	1
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	61.80	61.44	57.33
standard deviation	± 11.023	± 13.321	± 6.690
Gender categorical			
Units: Subjects			
Female	19	6	6
Male	22	12	3

Reporting group values	Total		
Number of subjects	216		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	139		
From 65-84 years	77		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	104		
Male	112		

End points

End points reporting groups

Reporting group title	FP-1305 (Bexmarilimab) 0.1 mg/kg
Reporting group description:	
Part I Dose-escalation FP-1305 0.1 mg/kg is administered in Q3W intervals FP-1305 (bexmarilimab)	
Reporting group title	FP-1305 (Bexmarilimab) 0.3 mg/kg
Reporting group description:	
Part I, Dose-escalation FP-1305 0.3 mg/kg is administered in Q3W intervals	
Reporting group title	FP-1305 (Bexmarilimab) 1 mg/kg
Reporting group description:	
Part I and II, Dose-escalation FP-1305 1 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)	
Reporting group title	FP-1305 (Bexmarilimab) 3 mg/kg
Reporting group description:	
Part I and II, Dose-escalation FP-1305 3 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)	
Reporting group title	FP-1305 (Bexmarilimab) 10 mg/kg
Reporting group description:	
Part I and II, Dose-escalation FP-1305 10 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)	
Reporting group title	FP-1305 (Bexmarilimab) 30 mg/kg
Reporting group description:	
Part II Dose-escalation FP-1305 30 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)	

Primary: Dose Limiting Toxicities (DLT) in the Trial Subjects.

End point title	Dose Limiting Toxicities (DLT) in the Trial Subjects.[1]
End point description:	
Tolerable dose(s) will be determined by the TITE-CRM based on the occurrence/non-occurrence of dose limiting toxicities in the trial subjects.	
End point type	Primary
End point timeframe:	
up to 1 year	

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: DLT were listed as descriptive statistics with no statistical analyses conducted.

End point values	FP-1305 (Bexmarilimab) 0.1 mg/kg	FP-1305 (Bexmarilimab) 0.3 mg/kg	FP-1305 (Bexmarilimab) 1 mg/kg	FP-1305 (Bexmarilimab) 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	13	130	41
Units: DLT				
number (not applicable)	0	0	0	0

End point values	FP-1305 (Bexmarilimab) 10 mg/kg	FP-1305 (Bexmarilimab) 30 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	9		
Units: DLT				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Incidence of Treatment Emergent Adverse Events (Safety and Tolerability)

End point title	Incidence of Treatment Emergent Adverse Events (Safety and Tolerability)[2]

End point description:

Number of adverse events and serious adverse events. Adverse events are collected, graded and reported according to the National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 5.0.

End point type	Primary

End point timeframe:

up to 6 years

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: TEAE were listed as descriptive statistics with no statistical analyses conducted.

End point values	FP-1305 (Bexmarilimab) 0.1 mg/kg	FP-1305 (Bexmarilimab) 0.3 mg/kg	FP-1305 (Bexmarilimab) 1 mg/kg	FP-1305 (Bexmarilimab) 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	13	130	41
Units: subjects				
number (not applicable)	5	13	122	38

End point values	FP-1305 (Bexmarilimab) 10 mg/kg	FP-1305 (Bexmarilimab) 30 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	9		
Units: subjects				
number (not applicable)	17	9		

Statistical analyses

No statistical analyses for this end point

Primary: The Response (ORR, CBR and irORR) to the Treatment.

End point title	The Response (ORR, CBR and irORR) to the Treatment.[3]

End point description:

The objective response rate (ORR), clinical benefit rate (CBR) and immune-related ORR (irORR) to the treatment will be determined by tumour imaging (tumor size) according to RECIST v.1.1. Results from each tumour type, dose level and dosing frequency will be reported separately.

End point type	Primary

End point timeframe:

up to 6 years

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Response were listed as descriptive statistics with no statistical analyses conducted.

End point values	FP-1305 (Bexmarilimab) 0.1 mg/kg	FP-1305 (Bexmarilimab) 0.3 mg/kg	FP-1305 (Bexmarilimab) 1 mg/kg	FP-1305 (Bexmarilimab) 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	13	130	41
Units: subjects				
number (not applicable)				
Objective response rate (ORR)	0	1	0	0
Disease Control rate (DCR)	0	1	18	0

End point values	FP-1305 (Bexmarilimab) 10 mg/kg	FP-1305 (Bexmarilimab) 30 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	9		
Units: subjects				
number (not applicable)				
Objective response rate (ORR)	0	0		
Disease Control rate (DCR)	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: up to six years	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups	
Reporting group title	FP-1305 (Bexmarilimab) 0.1 mg/kg
Reporting group description: Part I Dose-escalation FP-1305 0.1 mg/kg is administered in Q3W intervals FP-1305 (bexmarilimab)	
Reporting group title	FP-1305 (Bexmarilimab) 0.3 mg/kg
Reporting group description: Part I, Dose-escalation FP-1305 0.3 mg/kg is administered in Q3W intervals	
Reporting group title	FP-1305 (Bexmarilimab) 1 mg/kg
Reporting group description: Part I and II, Dose-escalation FP-1305 1 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)	
Reporting group title	FP-1305 (Bexmarilimab) 3 mg/kg
Reporting group description: Part I and II, Dose-escalation FP-1305 3 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)	
Reporting group title	FP-1305 (Bexmarilimab) 10 mg/kg
Reporting group description: Part I and II, Dose-escalation FP-1305 10 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)	
Reporting group title	FP-1305 (Bexmarilimab) 30 mg/kg
Reporting group description: Part II Dose-escalation FP-1305 30 mg/kg is administered in Q3W, Q2W or Q1W intervals FP-1305 (bexmarilimab)	

Serious adverse events	FP-1305 (Bexmarilimab) 0.1 mg/kg	FP-1305 (Bexmarilimab) 0.3 mg/kg	FP-1305 (Bexmarilimab) 1 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)	1 / 13 (7.69%)	57 / 130 (43.85%)
number of deaths (all causes)	0	0	12
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to meninges			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to oesophagus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
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 malignant			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
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 necrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
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			
Death			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	12 / 130 (9.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 12
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 5 (20.00%)	0 / 13 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	4 / 130 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated lung disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Transaminases increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	3 / 130 (2.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Lower limb fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Spinal fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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			
Spinal cord compression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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 encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hydrocephalus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Motor dysfunction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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			
Ascites			
subjects affected / exposed	2 / 5 (40.00%)	0 / 13 (0.00%)	5 / 130 (3.85%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	5 / 130 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	3 / 130 (2.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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 / 5 (0.00%)	0 / 13 (0.00%)	2 / 130 (1.54%)
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 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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 pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Induced Liver Injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
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 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Renal and urinary disorders			
Renal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenocortical insufficiency acute			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Biliary sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected seroma			
subjects affected / exposed	1 / 5 (20.00%)	0 / 13 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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 syncytial virus infection			

subjects affected / exposed	0 / 5 (0.00%)	1 / 13 (7.69%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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 viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 130 (0.77%)
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	FP-1305 (Bexmarilimab) 3 mg/kg	FP-1305 (Bexmarilimab) 10 mg/kg	FP-1305 (Bexmarilimab) 30 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 41 (31.71%)	10 / 18 (55.56%)	4 / 9 (44.44%)
number of deaths (all causes)	3	3	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 41 (0.00%)	1 / 18 (5.56%)	0 / 9 (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
Abdominal pain			

subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to meninges			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to oesophagus			
subjects affected / exposed	0 / 41 (0.00%)	1 / 18 (5.56%)	0 / 9 (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
Pericardial effusion malignant			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 adenocarcinoma			
subjects affected / exposed	0 / 41 (0.00%)	1 / 18 (5.56%)	0 / 9 (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
Tumour necrosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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			
Haematoma			
subjects affected / exposed	0 / 41 (0.00%)	1 / 18 (5.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Death			
subjects affected / exposed	3 / 41 (7.32%)	3 / 18 (16.67%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 3	0 / 0
Pyrexia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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			
Pleural effusion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 distress			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 / 41 (0.00%)	0 / 18 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Immune-mediated lung disease			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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			
Transaminases increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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			
Lower limb fracture			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			

subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 tamponade			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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			
Spinal cord compression			
subjects affected / exposed	1 / 41 (2.44%)	1 / 18 (5.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 encephalopathy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	1 / 41 (2.44%)	0 / 18 (0.00%)	0 / 9 (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
Motor dysfunction			

subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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			
Ascites			
subjects affected / exposed	2 / 41 (4.88%)	1 / 18 (5.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 / 41 (4.88%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	2 / 41 (4.88%)	0 / 18 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 41 (0.00%)	1 / 18 (5.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 41 (2.44%)	1 / 18 (5.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 41 (0.00%)	1 / 18 (5.56%)	0 / 9 (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
Nausea			
subjects affected / exposed	1 / 41 (2.44%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 / 41 (0.00%)	1 / 18 (5.56%)	0 / 9 (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
Gastric haemorrhage			
subjects affected / exposed	0 / 41 (0.00%)	1 / 18 (5.56%)	0 / 9 (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
Gastric ulcer			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 41 (0.00%)	2 / 18 (11.11%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hepatic pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Induced Liver Injury			
subjects affected / exposed	1 / 41 (2.44%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	1 / 41 (2.44%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 41 (0.00%)	2 / 18 (11.11%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal disorder			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenocortical insufficiency acute			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 41 (4.88%)	0 / 18 (0.00%)	0 / 9 (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

Bone pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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			
Biliary sepsis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected seroma			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 syncytial virus infection			

subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
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 viral			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	FP-1305 (Bexmarilimab) 0.1 mg/kg	FP-1305 (Bexmarilimab) 0.3 mg/kg	FP-1305 (Bexmarilimab) 1 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	13 / 13 (100.00%)	122 / 130 (93.85%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
subjects affected / exposed	1 / 5 (20.00%)	0 / 13 (0.00%)	9 / 130 (6.92%)
occurrences (all)	1	0	11
Vascular disorders			
Vascular disorders			

subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	13 / 130 (10.00%)
occurrences (all)	0	0	13
General disorders and administration site conditions			
General disorders and administration site conditions			
subjects affected / exposed	3 / 5 (60.00%)	8 / 13 (61.54%)	57 / 130 (43.85%)
occurrences (all)	6	15	99
Respiratory, thoracic and mediastinal disorders			
Respiratory, thoracic and mediastinal disorders			
subjects affected / exposed	1 / 5 (20.00%)	4 / 13 (30.77%)	21 / 130 (16.15%)
occurrences (all)	1	5	30
Investigations			
Investigations			
subjects affected / exposed	1 / 5 (20.00%)	4 / 13 (30.77%)	40 / 130 (30.77%)
occurrences (all)	1	10	104
Injury, poisoning and procedural complications			
Injury, poisoning and procedural complications			
subjects affected / exposed	0 / 5 (0.00%)	2 / 13 (15.38%)	5 / 130 (3.85%)
occurrences (all)	0	2	8
Nervous system disorders			
Nervous system disorders			
subjects affected / exposed	0 / 5 (0.00%)	3 / 13 (23.08%)	14 / 130 (10.77%)
occurrences (all)	0	5	25
Blood and lymphatic system disorders			
Cardiac disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	3 / 130 (2.31%)
occurrences (all)	0	0	7
Blood and lymphatic disorders			
subjects affected / exposed	0 / 5 (0.00%)	2 / 13 (15.38%)	32 / 130 (24.62%)
occurrences (all)	0	3	52
Gastrointestinal disorders			
Gastrointestinal disorder			
subjects affected / exposed	2 / 5 (40.00%)	7 / 13 (53.85%)	49 / 130 (37.69%)
occurrences (all)	11	13	145
Hepatobiliary disorders			

Hepatobiliary disorders			
subjects affected / exposed	0 / 5 (0.00%)	2 / 13 (15.38%)	7 / 130 (5.38%)
occurrences (all)	0	2	16
Renal and urinary disorders			
Renal and urinary disorders			
subjects affected / exposed	0 / 5 (0.00%)	1 / 13 (7.69%)	7 / 130 (5.38%)
occurrences (all)	0	1	8
Endocrine disorders			
Endocrine disorder			
subjects affected / exposed	0 / 5 (0.00%)	1 / 13 (7.69%)	4 / 130 (3.08%)
occurrences (all)	0	3	4
Musculoskeletal and connective tissue disorders			
Musculoskeletal and connective tissue disorders			
subjects affected / exposed	1 / 5 (20.00%)	5 / 13 (38.46%)	25 / 130 (19.23%)
occurrences (all)	2	10	47
Infections and infestations			
Infections and infestations			
subjects affected / exposed	2 / 5 (40.00%)	2 / 13 (15.38%)	16 / 130 (12.31%)
occurrences (all)	5	3	22
Metabolism and nutrition disorders			
Metabolism and nutrition disorders			
subjects affected / exposed	1 / 5 (20.00%)	3 / 13 (23.08%)	36 / 130 (27.69%)
occurrences (all)	1	5	55

Non-serious adverse events	FP-1305 (Bexmarilimab) 3 mg/kg	FP-1305 (Bexmarilimab) 10 mg/kg	FP-1305 (Bexmarilimab) 30 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 41 (92.68%)	17 / 18 (94.44%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
subjects affected / exposed	4 / 41 (9.76%)	2 / 18 (11.11%)	0 / 9 (0.00%)
occurrences (all)	5	3	0
Vascular disorders			
Vascular disorders			
subjects affected / exposed	5 / 41 (12.20%)	2 / 18 (11.11%)	0 / 9 (0.00%)
occurrences (all)	5	5	0
General disorders and administration site conditions			

General disorders and administration site conditions			
subjects affected / exposed	16 / 41 (39.02%)	11 / 18 (61.11%)	6 / 9 (66.67%)
occurrences (all)	24	16	8
Respiratory, thoracic and mediastinal disorders			
Respiratory, thoracic and mediastinal disorders			
subjects affected / exposed	4 / 41 (9.76%)	3 / 18 (16.67%)	1 / 9 (11.11%)
occurrences (all)	5	3	3
Investigations			
Investigations			
subjects affected / exposed	10 / 41 (24.39%)	6 / 18 (33.33%)	3 / 9 (33.33%)
occurrences (all)	22	18	7
Injury, poisoning and procedural complications			
Injury, poisoning and procedural complications			
subjects affected / exposed	3 / 41 (7.32%)	1 / 18 (5.56%)	1 / 9 (11.11%)
occurrences (all)	4	1	1
Nervous system disorders			
Nervous system disorders			
subjects affected / exposed	6 / 41 (14.63%)	1 / 18 (5.56%)	6 / 9 (66.67%)
occurrences (all)	14	1	6
Blood and lymphatic system disorders			
Cardiac disorder			
subjects affected / exposed	1 / 41 (2.44%)	1 / 18 (5.56%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Blood and lymphatic disorders			
subjects affected / exposed	11 / 41 (26.83%)	6 / 18 (33.33%)	2 / 9 (22.22%)
occurrences (all)	15	11	2
Gastrointestinal disorders			
Gastrointestinal disorder			
subjects affected / exposed	20 / 41 (48.78%)	5 / 18 (27.78%)	5 / 9 (55.56%)
occurrences (all)	44	22	8
Hepatobiliary disorders			
Hepatobiliary disorders			
subjects affected / exposed	3 / 41 (7.32%)	1 / 18 (5.56%)	0 / 9 (0.00%)
occurrences (all)	4	1	0
Renal and urinary disorders			

Renal and urinary disorders			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Endocrine disorder			
subjects affected / exposed	0 / 41 (0.00%)	0 / 18 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Musculoskeletal and connective tissue disorders			
subjects affected / exposed	12 / 41 (29.27%)	5 / 18 (27.78%)	0 / 9 (0.00%)
occurrences (all)	18	8	0
Infections and infestations			
Infections and infestations			
subjects affected / exposed	7 / 41 (17.07%)	1 / 18 (5.56%)	2 / 9 (22.22%)
occurrences (all)	11	2	2
Metabolism and nutrition disorders			
Metabolism and nutrition disorders			
subjects affected / exposed	10 / 41 (24.39%)	8 / 18 (44.44%)	0 / 9 (0.00%)
occurrences (all)	26	12	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 December 2018	Protocol v3.0, 03Dec2018
05 September 2019	Protocol v5.0, 20Aug2019
05 December 2019	Protocol v6.0, 28Nov2019
14 October 2020	Protocol v8.0, 15Sep2020
23 June 2021	Protocol v10, 09Jun2021
09 March 2022	Protocol v11, 22Dec2021

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported