Clinical trial results:
A Phase 2, Multicenter, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Ledipasvir Fixed-Dose Combination + Ribavirin Administered in Subjects Infected with Chronic HCV who have Advanced Liver Disease or are Post-Liver Transplant

Summary

EudraCT number	2013-002802-30
Trial protocol	BE GB DE IT AT NL ES
Global end of trial date	27 August 2015

Results information

Result version number	v1 (current)
This version publication date	03 July 2016
First version publication date	03 July 2016

Trial information

Trial identification

Sponsor protocol code	GS-US-337-0124

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02010255
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Gilead Sciences
Sponsor organisation address	333 Lakeside Drive, Foster City, United States, 94404
Public contact	Clinical Trial Mailbox, Gilead Sciences International Ltd, ClinicalTrialDisclosures@gilead.com
Scientific contact	Clinical Trial Mailbox, Gilead Sciences International Ltd, ClinicalTrialDisclosures@gilead.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	27 August 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 August 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study was to evaluate ledipasvir/sofosbuvir (LDV/SOF) fixed-dose combination (FDC) plus ribavirin (RBV) in participants with advanced liver disease or posttransplant and chronic genotype 1 or 4 hepatitis C virus (HCV) infection.

CPT = Child-Pugh-Turcotte; FCH = fibrosing cholestatic hepatitis

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements.

This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 January 2014
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: 8
Country: Number of subjects enrolled	Spain: 52
Country: Number of subjects enrolled	United Kingdom: 36
Country: Number of subjects enrolled	Austria: 23
Country: Number of subjects enrolled	Belgium: 16
Country: Number of subjects enrolled	France: 32
Country: Number of subjects enrolled	Germany: 28
Country: Number of subjects enrolled	Italy: 23
Country: Number of subjects enrolled	Canada: 49
Country: Number of subjects enrolled	Australia: 27
Country: Number of subjects enrolled	Switzerland: 23
Country: Number of subjects enrolled	New Zealand: 16
Worldwide total number of subjects	333
EEA total number of subjects	218

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)	267
From 65 to 84 years	66
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in Europe, Canada, Australia, and New Zealand. The first participant was screened on 14 January 2014. The last study visit occurred on 27 August 2015.

Pre-assignment

Screening details:

Cohort A: decompensated cirrhosis [advanced liver disease], no prior liver transplant; Cohort B: post-liver transplant, with or without cirrhosis. Group assignment within cohorts was based on severity of liver impairment at screening (or presence of disease for FCH groups). Randomization was 1:1 within groups to 12 or 24 weeks of treatment.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort A, Group 1 (12 wk): CPT Class B (7-9)

Arm description:

LDV/SOF+RBV for 12 weeks in participants with CPT Class B (CPT score 7-9)

Arm type	Experimental
Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

LDV/SOF (90/400 mg) FDC tablet administered orally once daily

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

Dosage and administration details:

RBV tablets (starting at 600 mg, then adjusted ± based on tolerability [weight-based maximum: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg]) administered orally in a divided daily dose

Arm title	Cohort A, Group 1 (24 wk): CPT Class B (7-9)

Arm description:

LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class B (CPT score 7-9)

Arm type	Experimental
Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

LDV/SOF (90/400 mg) FDC tablet administered orally once daily

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

Dosage and administration details:

RBV tablets (starting at 600 mg, then adjusted ± based on tolerability [weight-based maximum: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg]) administered orally in a divided daily dose

Arm title	Cohort A, Group 2 (12 wk): CPT Class C (10-12)

Arm description:

LDV/SOF+RBV for 12 weeks in participants with CPT Class C (CPT score 10-12)

Arm type	Experimental
Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

LDV/SOF (90/400 mg) FDC tablet administered orally once daily

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

Dosage and administration details:

RBV tablets (starting at 600 mg, then adjusted ± based on tolerability [weight-based maximum: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg]) administered orally in a divided daily dose

Arm title	Cohort A, Group 2 (24 wk): CPT Class C (10-12)

Arm description:

LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class C (CPT score 10-12)

Arm type	Experimental
Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

LDV/SOF (90/400 mg) FDC tablet administered orally once daily

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

Dosage and administration details:

RBV tablets (starting at 600 mg, then adjusted ± based on tolerability [weight-based maximum: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg]) administered orally in a divided daily dose

Arm title	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis

Arm description:

LDV/SOF+RBV tablets for 12 weeks in participants with Fibrosis Stage F0-F3

Arm type	Experimental

Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

LDV/SOF (90/400 mg) FDC tablet administered orally once daily

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

Dosage and administration details:

RBV tablets (weight-based dosing: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg) administered orally in a divided daily dose

Arm title	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis

Arm description:

LDV/SOF+RBV 24 weeks in participants with Fibrosis Stage F0-F3

Arm type	Experimental
Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

LDV/SOF (90/400 mg) FDC tablet administered orally once daily

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

Dosage and administration details:

RBV tablets (weight-based dosing: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg) administered orally in a divided daily dose

Arm title	Cohort B, Group 4 (12 wk): CPT Class A (5-6)

Arm description:

LDV/SOF+RBV tablets for 12 weeks in participants with CPT Class A (CPT score 5-6)

Arm type	Experimental
Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

LDV/SOF (90/400 mg) FDC tablet administered orally once daily

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

Dosage and administration details:

RBV tablets (weight-based dosing: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg) administered orally in a

divided daily dose

Arm title	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Arm description: LDV/SOF+RBV for 24 weeks in participants with CPT Class A (CPT score 5-6)	
Arm type	Experimental
Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: LDV/SOF (90/400 mg) FDC tablet administered orally once daily	
Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: RBV tablets (weight-based dosing: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg) administered orally in a divided daily dose	
Arm title	Cohort B, Group 5 (12 wk): CPT Class B (7-9)
Arm description: LDV/SOF+RBV tablets for 12 weeks in participants with CPT Class B (CPT score 7-9)	
Arm type	Experimental
Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: LDV/SOF (90/400 mg) FDC tablet administered orally once daily	
Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: RBV tablets (starting at 600 mg, then adjusted ± based on tolerability [weight-based maximum: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg]) administered orally in a divided daily dose	
Arm title	Cohort B, Group 5 (24 wk): CPT Class B (7-9)
Arm description: LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class B (CPT score 7-9)	
Arm type	Experimental

Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

LDV/SOF (90/400 mg) FDC tablet administered orally once daily

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

Dosage and administration details:

RBV tablets (starting at 600 mg, then adjusted ± based on tolerability [weight-based maximum: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg]) administered orally in a divided daily dose

Arm title	Cohort B, Group 6 (12 wk): CPT Class C (10-12)

Arm description:

LDV/SOF+RBV tablets for 12 weeks in participants with CPT Class C (CPT score 10-12)

Arm type	Experimental
Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

LDV/SOF (90/400 mg) FDC tablet administered orally once daily

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

Dosage and administration details:

RBV tablets (starting at 600 mg, then adjusted ± based on tolerability [weight-based maximum: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg]) administered orally in a divided daily dose

Arm title	Cohort B, Group 6 (24 wk): CPT Class C (10-12)

Arm description:

LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class C (CPT score 10-12)

Arm type	Experimental
Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

LDV/SOF (90/400 mg) FDC tablet administered orally once daily

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

Dosage and administration details:

RBV tablets (starting at 600 mg, then adjusted ± based on tolerability [weight-based maximum: < 75

kg = 1000 mg, ≥ 75 kg = 1200 mg]) administered orally in a divided daily dose

Arm title	Cohort B, Group 7 (12 wk): FCH
Arm description:	
LDV/SOF+RBV tablets for 12 weeks in participants with fibrosing cholestatic hepatitis (FCH)	
Arm type	Experimental
Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
LDV/SOF (90/400 mg) FDC tablet administered orally once daily	
Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
RBV tablets (weight-based dosing: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg) administered orally in a divided daily dose	
Arm title	Cohort B, Group 7 (24 wk): FCH
Arm description:	
LDV/SOF+RBV tablets for 24 weeks in participants with FCH	
Arm type	Experimental
Investigational medicinal product name	Ledipasvir/sofosbuvir
Investigational medicinal product code	
Other name	Harvoni®, GS-5885/GS-7977
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
LDV/SOF (90/400 mg) FDC tablet administered orally once daily	
Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
RBV tablets (weight-based dosing: < 75 kg = 1000 mg, ≥ 75 kg = 1200 mg) administered orally in a divided daily dose	

Number of subjects in period 1	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)
Started	28	28	25
Completed	22	26	18
Not completed	6	2	7
Withdrew Consent	1	-	-
Adverse event, non-fatal	1	-	-
Death	-	1	4
Lost to follow-up	-	-	1
Lack of efficacy	4	1	2

Number of subjects in period 1	Cohort A, Group 2 (24 wk): CPT Class C (10-12)	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis
Started	26	52	49
Completed	20	48	49
Not completed	6	4	0
Withdrew Consent	1	-	-
Adverse event, non-fatal	-	-	-
Death	4	2	-
Lost to follow-up	-	1	-
Lack of efficacy	1	1	-

Number of subjects in period 1	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)	Cohort B, Group 5 (12 wk): CPT Class B (7-9)
Started	34	33	22
Completed	33	32	21
Not completed	1	1	1
Withdrew Consent	-	-	-
Adverse event, non-fatal	-	-	-
Death	1	1	1
Lost to follow-up	-	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Started	23	3	5
Completed	23	1	4
Not completed	0	2	1
Withdrew Consent	-	-	-
Adverse event, non-fatal	-	-	-
Death	-	1	1
Lost to follow-up	-	-	-
Lack of efficacy	-	1	-

Number of subjects in period 1	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH
Started	3	2
Completed	3	2
Not completed	0	0
Withdrew Consent	-	-
Adverse event, non-fatal	-	-
Death	-	-
Lost to follow-up	-	-
Lack of efficacy	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Cohort A, Group 1 (12 wk): CPT Class B (7-9)
Reporting group description: LDV/SOF+RBV for 12 weeks in participants with CPT Class B (CPT score 7-9)	
Reporting group title	Cohort A, Group 1 (24 wk): CPT Class B (7-9)
Reporting group description: LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class B (CPT score 7-9)	
Reporting group title	Cohort A, Group 2 (12 wk): CPT Class C (10-12)
Reporting group description: LDV/SOF+RBV for 12 weeks in participants with CPT Class C (CPT score 10-12)	
Reporting group title	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Reporting group description: LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class C (CPT score 10-12)	
Reporting group title	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis
Reporting group description: LDV/SOF+RBV tablets for 12 weeks in participants with Fibrosis Stage F0-F3	
Reporting group title	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis
Reporting group description: LDV/SOF+RBV 24 weeks in participants with Fibrosis Stage F0-F3	
Reporting group title	Cohort B, Group 4 (12 wk): CPT Class A (5-6)
Reporting group description: LDV/SOF+RBV tablets for 12 weeks in participants with CPT Class A (CPT score 5-6)	
Reporting group title	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Reporting group description: LDV/SOF+RBV for 24 weeks in participants with CPT Class A (CPT score 5-6)	
Reporting group title	Cohort B, Group 5 (12 wk): CPT Class B (7-9)
Reporting group description: LDV/SOF+RBV tablets for 12 weeks in participants with CPT Class B (CPT score 7-9)	
Reporting group title	Cohort B, Group 5 (24 wk): CPT Class B (7-9)
Reporting group description: LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class B (CPT score 7-9)	
Reporting group title	Cohort B, Group 6 (12 wk): CPT Class C (10-12)
Reporting group description: LDV/SOF+RBV tablets for 12 weeks in participants with CPT Class C (CPT score 10-12)	
Reporting group title	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Reporting group description: LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class C (CPT score 10-12)	
Reporting group title	Cohort B, Group 7 (12 wk): FCH
Reporting group description: LDV/SOF+RBV tablets for 12 weeks in participants with fibrosing cholestatic hepatitis (FCH)	
Reporting group title	Cohort B, Group 7 (24 wk): FCH
Reporting group description: LDV/SOF+RBV tablets for 24 weeks in participants with FCH	

Reporting group values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)
Number of subjects	28	28	25

Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	55	56	58
standard deviation	± 9.9	± 8.6	± 8.1
Gender categorical Units: Subjects			
Female	5	9	10
Male	23	19	15
Ethnicity Units: Subjects			
Hispanic or Latino	6	6	3
Not Hispanic or Latino	22	22	22
Unknown or not reported	0	0	0
Race Units: Subjects			
Black or African American	1	0	1
White	25	28	23
Asian	0	0	0
Native Hawaiian or Pacific Islander	1	0	0
Other	1	0	1
HCV RNA Category Units: Subjects			
< 800,000 IU/mL	11	14	16
≥ 800,000 IU/mL	17	14	9
HCV Genotype Units: Subjects			
Genotype 1a	13	12	13
Genotype 1b	12	13	11
Genotype 4	3	3	1
IL28b Status			
The CC, CT, and TT alleles are different forms of the IL28b gene.			
Units: Subjects			
CC	6	9	7
CT	18	10	10
TT	4	9	8
Cirrhosis Status Units: Subjects			
No	0	0	0
Yes	28	28	25
HCV RNA Units: log10 IU/mL			
arithmetic mean	6	5.9	5.6
standard deviation	± 0.49	± 0.56	± 0.58

Reporting group values	Cohort A, Group 2 (24 wk): CPT Class C (10-12)	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis
Number of subjects	26	52	49

Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	54	58	59
standard deviation	± 10.7	± 7.9	± 6.9
Gender categorical Units: Subjects			
Female	6	11	10
Male	20	41	39
Ethnicity Units: Subjects			
Hispanic or Latino	8	4	8
Not Hispanic or Latino	18	48	41
Unknown or not reported	0	0	0
Race Units: Subjects			
Black or African American	1	1	0
White	25	50	47
Asian	0	0	1
Native Hawaiian or Pacific Islander	0	0	0
Other	0	1	1
HCV RNA Category Units: Subjects			
< 800,000 IU/mL	17	12	5
≥ 800,000 IU/mL	9	40	44
HCV Genotype Units: Subjects			
Genotype 1a	12	27	29
Genotype 1b	11	18	15
Genotype 4	3	7	5
IL28b Status			
The CC, CT, and TT alleles are different forms of the IL28b gene.			
Units: Subjects			
CC	4	9	10
CT	15	31	25
TT	7	12	14
Cirrhosis Status Units: Subjects			
No	0	52	49
Yes	26	0	0
HCV RNA Units: log10 IU/mL			
arithmetic mean	5.7	6.4	6.5
standard deviation	± 0.44	± 0.72	± 0.44

Reporting group values	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)	Cohort B, Group 5 (12 wk): CPT Class B (7-9)
Number of subjects	34	33	22

Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	57	62	58
standard deviation	± 7.2	± 7.5	± 8
Gender categorical Units: Subjects			
Female	6	7	7
Male	28	26	15
Ethnicity Units: Subjects			
Hispanic or Latino	5	7	3
Not Hispanic or Latino	29	26	19
Unknown or not reported	0	0	0
Race Units: Subjects			
Black or African American	0	0	0
White	33	30	21
Asian	0	3	0
Native Hawaiian or Pacific Islander	1	0	0
Other	0	0	1
HCV RNA Category Units: Subjects			
< 800,000 IU/mL	9	5	5
≥ 800,000 IU/mL	25	28	17
HCV Genotype Units: Subjects			
Genotype 1a	14	13	11
Genotype 1b	16	15	9
Genotype 4	4	5	2
IL28b Status			
The CC, CT, and TT alleles are different forms of the IL28b gene.			
Units: Subjects			
CC	3	7	3
CT	23	21	12
TT	8	5	7
Cirrhosis Status Units: Subjects			
No	0	0	0
Yes	34	33	22
HCV RNA Units: log10 IU/mL			
arithmetic mean	6.3	6.5	6.1
standard deviation	± 0.58	± 0.55	± 0.78

Reporting group values	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Number of subjects	23	3	5

Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	60	62	62
standard deviation	± 10.2	± 4.6	± 9.2
Gender categorical Units: Subjects			
Female	8	1	0
Male	15	2	5
Ethnicity Units: Subjects			
Hispanic or Latino	4	1	2
Not Hispanic or Latino	19	2	3
Unknown or not reported	0	0	0
Race Units: Subjects			
Black or African American	1	0	0
White	21	3	5
Asian	1	0	0
Native Hawaiian or Pacific Islander	0	0	0
Other	0	0	0
HCV RNA Category Units: Subjects			
< 800,000 IU/mL	9	2	0
≥ 800,000 IU/mL	14	1	5
HCV Genotype Units: Subjects			
Genotype 1a	13	1	1
Genotype 1b	7	1	4
Genotype 4	3	1	0
IL28b Status			
The CC, CT, and TT alleles are different forms of the IL28b gene.			
Units: Subjects			
CC	5	0	3
CT	11	2	2
TT	7	1	0
Cirrhosis Status Units: Subjects			
No	0	0	0
Yes	23	3	5
HCV RNA Units: log10 IU/mL			
arithmetic mean	6.2	6	6.5
standard deviation	± 0.85	± 0.49	± 0.5

Reporting group values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH	Total
Number of subjects	3	2	333

Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	58	53	
standard deviation	± 2.6	± 2.8	-
Gender categorical Units: Subjects			
Female	1	1	82
Male	2	1	251
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	57
Not Hispanic or Latino	3	2	276
Unknown or not reported	0	0	0
Race Units: Subjects			
Black or African American	0	0	5
White	2	1	314
Asian	1	1	7
Native Hawaiian or Pacific Islander	0	0	2
Other	0	0	5
HCV RNA Category Units: Subjects			
< 800,000 IU/mL	0	1	106
≥ 800,000 IU/mL	3	1	227
HCV Genotype Units: Subjects			
Genotype 1a	2	2	163
Genotype 1b	1	0	133
Genotype 4	0	0	37
IL28b Status			
The CC, CT, and TT alleles are different forms of the IL28b gene.			
Units: Subjects			
CC	0	1	67
CT	3	1	184
TT	0	0	82
Cirrhosis Status Units: Subjects			
No	3	2	106
Yes	0	0	227
HCV RNA Units: log10 IU/mL			
arithmetic mean	7.3	6	
standard deviation	± 0.72	± 0.41	-

End points

End points reporting groups

Reporting group title	Cohort A, Group 1 (12 wk): CPT Class B (7-9)
Reporting group description: LDV/SOF+RBV for 12 weeks in participants with CPT Class B (CPT score 7-9)	
Reporting group title	Cohort A, Group 1 (24 wk): CPT Class B (7-9)
Reporting group description: LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class B (CPT score 7-9)	
Reporting group title	Cohort A, Group 2 (12 wk): CPT Class C (10-12)
Reporting group description: LDV/SOF+RBV for 12 weeks in participants with CPT Class C (CPT score 10-12)	
Reporting group title	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Reporting group description: LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class C (CPT score 10-12)	
Reporting group title	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis
Reporting group description: LDV/SOF+RBV tablets for 12 weeks in participants with Fibrosis Stage F0-F3	
Reporting group title	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis
Reporting group description: LDV/SOF+RBV 24 weeks in participants with Fibrosis Stage F0-F3	
Reporting group title	Cohort B, Group 4 (12 wk): CPT Class A (5-6)
Reporting group description: LDV/SOF+RBV tablets for 12 weeks in participants with CPT Class A (CPT score 5-6)	
Reporting group title	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Reporting group description: LDV/SOF+RBV for 24 weeks in participants with CPT Class A (CPT score 5-6)	
Reporting group title	Cohort B, Group 5 (12 wk): CPT Class B (7-9)
Reporting group description: LDV/SOF+RBV tablets for 12 weeks in participants with CPT Class B (CPT score 7-9)	
Reporting group title	Cohort B, Group 5 (24 wk): CPT Class B (7-9)
Reporting group description: LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class B (CPT score 7-9)	
Reporting group title	Cohort B, Group 6 (12 wk): CPT Class C (10-12)
Reporting group description: LDV/SOF+RBV tablets for 12 weeks in participants with CPT Class C (CPT score 10-12)	
Reporting group title	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Reporting group description: LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class C (CPT score 10-12)	
Reporting group title	Cohort B, Group 7 (12 wk): FCH
Reporting group description: LDV/SOF+RBV tablets for 12 weeks in participants with fibrosing cholestatic hepatitis (FCH)	
Reporting group title	Cohort B, Group 7 (24 wk): FCH
Reporting group description: LDV/SOF+RBV tablets for 24 weeks in participants with FCH	
Subject analysis set title	All LDV/SOF+RBV (pTVR)
Subject analysis set type	Full analysis
Subject analysis set description: Includes participants who had a liver transplant while on study if their last observed HCV RNA measurement prior to transplant was < LLOQ. Participants who received a transplant from an HCV-infected donor were excluded from analysis.	

Subject analysis set title	Cohort A: Baseline CPT Class B (12 wk)
Subject analysis set type	Full analysis

Subject analysis set description:

Includes participants in Cohort A (12 wk) with CPT score B at baseline (randomization was based on screening measurement), and who had CPT score assessments at both baseline and Posttreatment Week 4.

Subject analysis set title	Cohort A: Baseline CPT Class B (24 wk)
Subject analysis set type	Full analysis

Subject analysis set description:

Includes participants in Cohort A (24 wk) with CPT score B at baseline (randomization was based on screening measurement), and who had CPT score assessments at both baseline and Posttreatment Week 4.

Subject analysis set title	Cohort A: Baseline CPT Class C (12 wk)
Subject analysis set type	Full analysis

Subject analysis set description:

Includes participants in Cohort A (12 wk) with CPT score C at baseline (randomization was based on screening measurement), and who had CPT score assessments at both baseline and Posttreatment Week 4.

Subject analysis set title	Cohort A: Baseline CPT Class C (24 wk)
Subject analysis set type	Full analysis

Subject analysis set description:

Includes participants in Cohort A (24 wk) with CPT score C at baseline (randomization was based on screening measurement), and who had CPT score assessments at both baseline and Posttreatment Week 4.

Subject analysis set title	Cohort B: Baseline CPT Class A (12 wk)
Subject analysis set type	Full analysis

Subject analysis set description:

Includes participants in Cohort B (12 wk) with CPT score A at baseline (randomization was based on screening measurement), and who had CPT score assessments at both baseline and Posttreatment Week 4.

Subject analysis set title	Cohort B: Baseline CPT Class A (24 wk)
Subject analysis set type	Full analysis

Subject analysis set description:

Includes participants in Cohort B (24 wk) with CPT score A at baseline (randomization was based on screening measurement), and who had CPT score assessments at both baseline and Posttreatment Week 4.

Subject analysis set title	Cohort B: Baseline CPT Class B (12 wk)
Subject analysis set type	Full analysis

Subject analysis set description:

Includes participants in Cohort B (12 wk) with CPT score B at baseline (randomization was based on screening measurement), and who had CPT score assessments at both baseline and Posttreatment Week 4.

Subject analysis set title	Cohort B: Baseline CPT Class B (24 wk)
Subject analysis set type	Full analysis

Subject analysis set description:

Includes participants in Cohort B (24 wk) with CPT score B at baseline (randomization was based on screening measurement), and who had CPT score assessments at both baseline and Posttreatment Week 4.

Subject analysis set title	Cohort B: Baseline CPT Class C (12 wk)
Subject analysis set type	Full analysis

Subject analysis set description:

Includes participants in Cohort B (12 wk) with CPT score C at baseline (randomization was based on screening measurement), and who had CPT score assessments at both baseline and Posttreatment Week 4.

Subject analysis set title	Cohort B: Baseline CPT Class C (24 wk)
Subject analysis set type	Full analysis

Subject analysis set description:

Includes participants in Cohort B (24 wk) with CPT score C at baseline (randomization was based on screening measurement), and who had CPT score assessments at both baseline and Posttreatment Week 4.

Primary: Percentage of Participants With Sustained Virologic Response (SVR) 12 Weeks After Discontinuation of Therapy (SVR12)

End point title	Percentage of Participants With Sustained Virologic Response (SVR) 12 Weeks After Discontinuation of Therapy (SVR12)[1]

End point description:

SVR12 was defined as HCV RNA < the lower limit of quantitation (LLOQ; ie, 15 IU/mL) at 12 weeks after stopping study treatment.

Full Analysis Set: participants who were randomized and received at least one dose of study drug. Participants in Cohort A who received a liver transplant prior to the lower bound of the Posttreatment Week 12 visit were not included in the analysis.

End point type	Primary

End point timeframe:

Posttreatment Week 12

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: No statistical analysis was planned or performed.

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	25	21	25
Units: percentage of participants				
number (not applicable)	84.6	96	81	76

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	33
Units: percentage of participants				
number (not applicable)	94.2	100	97.1	97

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	5
Units: percentage of participants				
number (not applicable)	95.5	100	33.3	80

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Who Discontinued Study Drug Due to an Adverse Event

End point title	Percentage of Participants Who Discontinued Study Drug Due to an Adverse Event[2]

End point description:

Safety Analysis Set: participants who were randomized and received at least one dose of study drug

End point type	Primary

End point timeframe:

Up to 24 weeks

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: No statistical analysis was planned or performed.

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	28	25	26
Units: percentage of participants				
number (not applicable)				
Discontinued LDV/SOF	3.6	3.6	0	7.7
Discontinued Any Study Drug	3.6	7.1	16	23.1

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	33
Units: percentage of participants				
number (not applicable)				
Discontinued LDV/SOF	1.9	0	0	3

Discontinued Any Study Drug	5.8	6.1	0	15.2

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	5
Units: percentage of participants				
number (not applicable)				
Discontinued LDV/SOF	0	0	0	20
Discontinued Any Study Drug	18.2	17.4	33.3	20

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)				
Discontinued LDV/SOF	0	0		
Discontinued Any Study Drug	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With SVR 2 Weeks After Discontinuation of Therapy (SVR2)

End point title	Percentage of Participants With SVR 2 Weeks After Discontinuation of Therapy (SVR2)

End point description:

Percentage of Participants With SVR 2 Weeks After Discontinuation of Therapy (SVR2).

Full Analysis Set. Participants in Cohort A who received a liver transplant prior to the lower bound of the Posttreatment Week 2 visit were not included in the analysis.

End point type	Secondary

End point timeframe:

Posttreatment Week 2

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	26	23	25
Units: percentage of participants				
number (not applicable)	96.2	100	91.3	80

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	33
Units: percentage of participants				
number (not applicable)	98.1	100	100	97

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	5
Units: percentage of participants				
number (not applicable)	95.5	100	100	80

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With SVR 4 Weeks After Discontinuation of Therapy (SVR4)

End point title	Percentage of Participants With SVR 4 Weeks After Discontinuation of Therapy (SVR4)

End point description:

SVR4 was defined as HCV RNA < LLOQ at 4 weeks after stopping study treatment.

Full Analysis Set. Participants in Cohort A who received a liver transplant prior to the lower bound of the Posttreatment Week 4 visit were not included in the analysis.

End point type	Secondary
End point timeframe:	
Posttreatment Week 4	

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	26	22	25
Units: percentage of participants				
number (not applicable)	88.5	100	90.9	80

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	33
Units: percentage of participants				
number (not applicable)	94.2	100	97.1	97

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	5
Units: percentage of participants				
number (not applicable)	95.5	100	100	80

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With SVR 8 Weeks After Discontinuation of Therapy (SVR8)

End point title	Percentage of Participants With SVR 8 Weeks After Discontinuation of Therapy (SVR8)

End point description:

SVR8 was defined as HCV RNA < LLOQ at 8 weeks after stopping study treatment.

Full Analysis Set. Participants in Cohort A who received a liver transplant prior to the lower bound of the Posttreatment Week 8 visit were not included in the analysis.

End point type	Secondary

End point timeframe:

Posttreatment Week 8

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	26	22	25
Units: percentage of participants				
number (not applicable)	84.6	96.2	81.8	80

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	33
Units: percentage of participants				
number (not applicable)	94.2	100	97.1	97

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	5
Units: percentage of participants				
number (not applicable)	95.5	100	33.3	80

End point values	Cohort B,	Cohort B,		

	Group 7 (12 wk): FCH	Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With SVR 24 Weeks After Discontinuation of Therapy (SVR24)

End point title	Percentage of Participants With SVR 24 Weeks After Discontinuation of Therapy (SVR24)

End point description:

SVR24 was defined as HCV RNA < LLOQ at 24 weeks after stopping study treatment.

Full Analysis Set. Participants in Cohort A and 1 participant in Cohort B who received a liver transplant prior to the lower bound of the Posttreatment Week 24 visit were not included in the analysis.

End point type	Secondary

End point timeframe:

Posttreatment Week 24

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	25	20	25
Units: percentage of participants				
number (not applicable)	84	96	80	76

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	33
Units: percentage of participants				
number (not applicable)	94.2	100	97.1	97

End point values	Cohort B, Group 5 (12 wk): CPT Class	Cohort B, Group 5 (24 wk): CPT Class	Cohort B, Group 6 (12 wk): CPT Class	Cohort B, Group 6 (24 wk): CPT Class

	B (7-9)	B (7-9)	C (10-12)	C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	22	3	5
Units: percentage of participants				
number (not applicable)	95.5	100	33.3	80

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Virologic Failure

End point title	Percentage of Participants With Virologic Failure

End point description:

Virologic failure was defined as either on-treatment virologic failure or virologic relapse. On-treatment virologic failure = either breakthrough (confirmed HCV RNA ≥ LLOQ after having previously had HCV RNA < LLOQ on 2 consecutive measurements while on treatment), or rebound (confirmed > 1 log10 IU/mL increase in HCV RNA from nadir while on treatment). Virologic relapse = confirmed HCV RNA ≥ LLOQ during the posttreatment period having achieved HCV RNA < LLOQ at last on-treatment visit.

Full Analysis Set. Participants were excluded from the analysis if they received a liver transplant while on study (with HCV RNA <LLOQ at transplant) prior to lower bound of Posttreatment Week 12 visit window.

End point type	Secondary

End point timeframe:

Up to Posttreatment Week 24

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	25	21	25
Units: percentage of participants				
number (not applicable)	15.4	4	9.5	4

End point values	Cohort B, Group 3 (12	Cohort B, Group 3 (24	Cohort B, Group 4 (12	Cohort B, Group 4 (24

	wk): F0-F3 Fibrosis	wk): F0-F3 Fibrosis	wk): CPT Class A (5-6)	wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	33
Units: percentage of participants				
number (not applicable)	1.9	0	0	0

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	5
Units: percentage of participants				
number (not applicable)	0	0	33.3	0

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Posttransplant Virologic Response (pTVR) at Posttransplant Week 12

End point title	Percentage of Participants With Posttransplant Virologic Response (pTVR) at Posttransplant Week 12

End point description:

pTVR was defined as HCV RNA < LLOQ at Week 12 after transplant.

All participants in the analysis are presented in a single group, regardless of randomization group assignment. Participants who had a liver transplant while on study were analyzed if their last observed HCV RNA measurement prior to transplant was < LLOQ. Participants who received a transplant from an HCV-infected donor were excluded from the analysis.

End point type	Secondary

End point timeframe:

Posttransplant Week 12

End point values	All LDV/SOF+RBV (pTVR)			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: percentage of participants				
number (not applicable)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 1

End point title	Percentage of Participants With HCV RNA < LLOQ at Week 1
End point description: Full Analysis Set	
End point type	Secondary
End point timeframe: Week 1	

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	25	26
Units: percentage of participants				
number (not applicable)	3.8	3.7	12	3.8

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	33
Units: percentage of participants				
number (not applicable)	9.6	6.1	5.9	3

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	5

Units: percentage of participants				
number (not applicable)	0	8.7	0	0

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 2

End point title	Percentage of Participants With HCV RNA < LLOQ at Week 2
End point description: Full Analysis Set	
End point type	Secondary
End point timeframe: Week 2	

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	25	26
Units: percentage of participants				
number (not applicable)	26.9	37	40	38.5

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	33
Units: percentage of participants				
number (not applicable)	48.1	44.9	26.5	21.2

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	5
Units: percentage of participants				
number (not applicable)	31.8	30.4	0	0

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)	33.3	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 4

End point title	Percentage of Participants With HCV RNA < LLOQ at Week 4
End point description:	
Participants in the Full Analysis Set with available data were analyzed.	
End point type	Secondary
End point timeframe:	
Week 4	

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	25	26
Units: percentage of participants				
number (not applicable)	76.9	81.5	80	84.6

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	33

Units: percentage of participants				
number (not applicable)	84.6	91.8	67.6	81.8

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	4
Units: percentage of participants				
number (not applicable)	72.7	82.6	100	25

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 6

End point title	Percentage of Participants With HCV RNA < LLOQ at Week 6
End point description: Participants in the Full Analysis Set with available data were analyzed.	
End point type	Secondary
End point timeframe: Week 6	

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	24	25
Units: percentage of participants				
number (not applicable)	100	100	91.7	100

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	33
Units: percentage of participants				
number (not applicable)	98.1	100	100	97

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	4
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 8

End point title	Percentage of Participants With HCV RNA < LLOQ at Week 8

End point description:

Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Week 8

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	24	25
Units: percentage of participants				
number (not applicable)	100	100	100	96

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	32
Units: percentage of participants				
number (not applicable)	100	100	100	96.9

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	4
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 12

End point title	Percentage of Participants With HCV RNA < LLOQ at Week 12

End point description:

Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:
Week 12

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	24	24
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	49	34	32
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	4
Units: percentage of participants				
number (not applicable)	95.5	100	100	100

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: percentage of participants				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 16

End point title	Percentage of Participants With HCV RNA < LLOQ at Week 16[3]

End point description:

Participants in the Full Analysis Set who were randomized to a 24-week treatment group and had available data were analyzed. 12-week treatment groups (did not collect data past Week 12) are not presented in this table.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[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: 12-week treatment groups (did not collect data past Week 12) are not presented in this table.

End point values	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	22	49	32
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)	Cohort B, Group 7 (24 wk): FCH	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	4	2	
Units: percentage of participants				
number (not applicable)	100	100	100	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 20

End point title	Percentage of Participants With HCV RNA < LLOQ at Week 20[4]

End point description:

Participants in the Full Analysis Set who were randomized to a 24-week treatment group and had available data were analyzed. 12-week treatment groups (did not collect data past Week 12) are not presented in this table.

End point type	Secondary

End point timeframe:

Week 20

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: 12-week treatment groups (did not collect data past Week 12) are not presented in this table.

End point values	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	21	49	32
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)	Cohort B, Group 7 (24 wk): FCH	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	4	2	
Units: percentage of participants				
number (not applicable)	100	100	100	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 24

End point title	Percentage of Participants With HCV RNA < LLOQ at Week 24[5]

End point description:

Participants in the Full Analysis Set who were randomized to a 24-week treatment group and had available data were analyzed. 12-week treatment groups (did not collect data past Week 12) are not presented in this table.

End point type	Secondary

End point timeframe:

Week 24

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: 12-week treatment groups (did not collect data past Week 12) are not presented in this table.

End point values	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	21	49	32
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	Cohort B, Group 5 (24	Cohort B, Group 6 (24	Cohort B, Group 7 (24	

	wk): CPT Class B (7-9)	wk): CPT Class C (10-12)	wk): FCH	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	4	2	
Units: percentage of participants				
number (not applicable)	100	100	100	

Statistical analyses

No statistical analyses for this end point

Secondary: HCV RNA and Change From Baseline at Week 1

End point title	HCV RNA and Change From Baseline at Week 1
End point description:	
Participants in the Full Analysis Set with available data were analyzed.	
End point type	Secondary
End point timeframe:	
Baseline; Week 1	

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	24	25
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 1	2.44 (± 0.665)	2.47 (± 0.696)	2.32 (± 0.868)	2.5 (± 0.645)
Change at Week 1	-3.6 (± 0.535)	-3.39 (± 0.634)	-3.28 (± 0.735)	-3.2 (± 0.61)

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	33
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 1	2.38 (± 0.716)	2.38 (± 0.653)	2.64 (± 0.784)	2.81 (± 0.729)
Change at Week 1	-3.98 (± 0.611)	-4.12 (± 0.538)	-3.7 (± 0.489)	-3.65 (± 0.562)

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	5
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 1	2.63 (± 0.78)	2.75 (± 0.888)	2.97 (± 0.229)	3.73 (± 0.434)
Change at Week 1	-3.5 (± 0.666)	-3.44 (± 0.789)	-3.06 (± 0.645)	-2.74 (± 0.446)

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 1	2.91 (± 0.825)	2.28 (± 0.62)		
Change at Week 1	-4.4 (± 0.503)	-3.76 (± 0.213)		

Statistical analyses

No statistical analyses for this end point

Secondary: HCV RNA and Change From Baseline at Week 2

End point title	HCV RNA and Change From Baseline at Week 2
End point description:	
Participants in the Full Analysis Set with available data were analyzed.	
End point type	Secondary
End point timeframe:	
Baseline; Week 2	

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	25	26
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 2	1.76 (± 0.668)	1.7 (± 0.579)	1.71 (± 0.625)	1.72 (± 0.573)
Change at Week 2	-4.29 (± 0.534)	-4.17 (± 0.538)	-3.92 (± 0.61)	-3.99 (± 0.566)

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	48	33	33
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 2	1.62 (± 0.604)	1.49 (± 0.477)	1.92 (± 0.839)	1.97 (± 0.607)
Change at Week 2	-4.74 (± 0.733)	-5 (± 0.522)	-4.42 (± 0.729)	-4.48 (± 0.583)

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	5
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 2	1.86 (± 0.607)	2 (± 0.718)	2.08 (± 0.378)	2.81 (± 0.709)
Change at Week 2	-4.26 (± 0.708)	-4.2 (± 0.764)	-3.95 (± 0.796)	-3.66 (± 0.601)

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 2	1.85 (± 0.731)	1.65 (± 0.122)		
Change at Week 2	-5.46 (± 0.756)	-4.38 (± 0.285)		

Statistical analyses

No statistical analyses for this end point

Secondary: HCV RNA and Change From Baseline at Week 4

End point title	HCV RNA and Change From Baseline at Week 4
End point description:	
Participants in the Full Analysis Set with available data were analyzed.	
End point type	Secondary

End point timeframe:
Baseline; Week 4

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	24	25
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 4	1.26 (± 0.257)	1.2 (± 0.148)	1.23 (± 0.205)	1.18 (± 0.147)
Change at Week 4	-4.78 (± 0.43)	-4.66 (± 0.518)	-4.45 (± 0.521)	-4.52 (± 0.492)

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	32
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 4	1.23 (± 0.247)	1.18 (± 0.129)	1.29 (± 0.301)	1.21 (± 0.154)
Change at Week 4	-5.13 (± 0.721)	-5.32 (± 0.453)	-5.05 (± 0.526)	-5.25 (± 0.518)

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	4
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 4	1.25 (± 0.199)	1.32 (± 0.408)	1.15 (± 0)	1.56 (± 0.585)
Change at Week 4	-4.88 (± 0.762)	-4.87 (± 0.816)	-4.89 (± 0.49)	-4.91 (± 0.24)

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: log10 IU/mL				

arithmetic mean (standard deviation)				
Week 4	1.15 (± 0)	1.15 (± 0)		
Change at Week 4	-6.16 (± 0.725)	-4.89 (± 0.407)		

Statistical analyses

No statistical analyses for this end point

Secondary: HCV RNA and Change From Baseline at Week 6

End point title	HCV RNA and Change From Baseline at Week 6
End point description:	
Participants in the Full Analysis Set with available data were analyzed.	
End point type	Secondary
End point timeframe:	
Baseline; Week 6	

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	23	25
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 6	1.15 (± 0)	1.15 (± 0)	1.17 (± 0.102)	1.15 (± 0)
Change at Week 6	-4.9 (± 0.487)	-4.72 (± 0.535)	-4.51 (± 0.527)	-4.56 (± 0.445)

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	49	34	32
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 6	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)
Change at Week 6	-5.21 (± 0.728)	-5.35 (± 0.436)	-5.19 (± 0.577)	-5.31 (± 0.557)

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	4
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 6	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)
Change at Week 6	-4.98 (± 0.779)	-5.05 (± 0.851)	-4.89 (± 0.49)	-5.33 (± 0.574)

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 6	1.15 (± 0)	1.15 (± 0)		
Change at Week 6	-6.16 (± 0.725)	-4.89 (± 0.407)		

Statistical analyses

No statistical analyses for this end point

Secondary: HCV RNA and Change From Baseline at Week 8

End point title	HCV RNA and Change From Baseline at Week 8

End point description:

Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Week 8

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	24	24
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 8	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)
Change at Week 8	-4.9 (± 0.487)	-4.72 (± 0.535)	-4.53 (± 0.534)	-4.6 (± 0.393)

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	34	31
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 8	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)
Change at Week 8	-5.21 (± 0.722)	-5.35 (± 0.436)	-5.19 (± 0.577)	-5.31 (± 0.565)

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	23	3	4
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 8	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)
Change at Week 8	-4.98 (± 0.779)	-5.05 (± 0.851)	-4.89 (± 0.49)	-5.33 (± 0.574)

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 8	1.15 (± 0)	1.15 (± 0)		
Change at Week 8	-6.16 (± 0.725)	-4.89 (± 0.407)		

Statistical analyses

No statistical analyses for this end point

Secondary: HCV RNA and Change From Baseline at Week 12

End point title	HCV RNA and Change From Baseline at Week 12

End point description:

Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Week 12

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	24	24
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 12	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)
Change at Week 12	-4.9 (± 0.487)	-4.72 (± 0.535)	-4.53 (± 0.534)	-4.6 (± 0.393)

End point values	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	49	34	32
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 12	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)
Change at Week 12	-5.21 (± 0.729)	-5.35 (± 0.436)	-5.19 (± 0.577)	-5.3 (± 0.556)

End point values	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	23	3	4
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 12	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)	1.15 (± 0)
Change at Week 12	-4.98 (± 0.798)	-5.05 (± 0.851)	-4.89 (± 0.49)	-5.33 (± 0.574)

End point values	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
Week 12	1.15 (± 0)	1.15 (± 0)		

Change at Week 12	-6.16 (± 0.725)	-4.89 (± 0.407)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Decrease, No Change, or Increase Between Baseline and Posttreatment Week 4 in MELD Score

End point title	Percentage of Participants With a Decrease, No Change, or Increase Between Baseline and Posttreatment Week 4 in MELD Score[6]

End point description:

Model for End-Stage Liver Disease (MELD) scores are used to assess prognosis and suitability for liver transplantation. Scores can range from 6 to 40; higher scores/increased scores indicate greater severity of disease.

Full Analysis Set. Participants with cirrhosis were analyzed if they had measurements at both baseline and Posttreatment Week 4. Only groups with cirrhotic participants are presented.

End point type	Secondary

End point timeframe:

Baseline to Posttreatment Week 4

Notes:

[6] - 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: Only groups with cirrhotic participants are presented.

End point values	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)	Cohort A, Group 2 (24 wk): CPT Class C (10-12)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	22	21	20
Units: percentage of participants				
number (not applicable)				
Decrease	70.8	77.3	81	70
No Change	12.5	9.1	14.3	5
Increase	16.7	13.6	4.8	25

End point values	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)	Cohort B, Group 5 (12 wk): CPT Class B (7-9)	Cohort B, Group 5 (24 wk): CPT Class B (7-9)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	32	32	21	23
Units: percentage of participants				
number (not applicable)				
Decrease	28.1	62.5	66.7	65.2
No Change	31.3	18.8	14.3	17.4
Increase	40.6	18.8	19	17.4

End point values	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	4		
Units: percentage of participants				
number (not applicable)				
Decrease	50	75		
No Change	50	0		
Increase	0	25		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Decrease, No Change, or Increase Between Baseline and Posttreatment Week 4 in CPT Score

End point title	Percentage of Participants With a Decrease, No Change, or Increase Between Baseline and Posttreatment Week 4 in CPT Score

End point description:

CPT scores grade the severity of cirrhosis and are used to determine the need for liver transplantation. Scores can range from 5 to 15 (maximum score for entry into the study was 12); higher scores/increased scores indicate greater severity of disease. Groups are arranged by cohort, then by duration of treatment, then by CPT class at baseline.

Full Analysis Set. Cirrhotic participants were analyzed if they had measurements at both baseline and Posttreatment Week 4. Only groups with cirrhotic participants are presented.

End point type	Secondary

End point timeframe:

Baseline to Posttreatment Week 4

End point values	Cohort A: Baseline CPT Class B (12 wk)	Cohort A: Baseline CPT Class B (24 wk)	Cohort A: Baseline CPT Class C (12 wk)	Cohort A: Baseline CPT Class C (24 wk)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	28	23	17	19
Units: percentage of participants				
number (not applicable)				
Decrease	64.3	87	82.4	73.7
No Change	28.6	13	11.8	26.3
Increase	7.1	0	5.9	0

End point values	Cohort B: Baseline CPT Class A (12 wk)	Cohort B: Baseline CPT Class A (24 wk)	Cohort B: Baseline CPT Class B (12 wk)	Cohort B: Baseline CPT Class B (24 wk)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	35	34	18	20
Units: percentage of participants				
number (not applicable)				
Decrease	28.6	23.5	61.1	85
No Change	68.6	61.8	33.3	10
Increase	2.9	14.7	5.6	5

End point values	Cohort B: Baseline CPT Class C (12 wk)	Cohort B: Baseline CPT Class C (24 wk)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	5		
Units: percentage of participants				
number (not applicable)				
Decrease	100	80		
No Change	0	20		
Increase	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 24 weeks on treatment plus 30 days

Adverse event reporting additional description:

Safety Analysis Set: participants who were enrolled and received at least one dose of study drug

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	Cohort A, Group 1 (12 wk): CPT Class B (7-9)

Reporting group description:

LDV/SOF+RBV for 12 weeks in participants with CPT Class B (CPT score 7-9)

Reporting group title	Cohort A, Group 1 (24 wk): CPT Class B (7-9)

Reporting group description:

LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class B (CPT score 7-9)

Reporting group title	Cohort A, Group 2 (12 wk): CPT Class C (10-12)

Reporting group description:

LDV/SOF+RBV for 12 weeks in participants with CPT Class C (CPT score 10-12)

Reporting group title	Cohort A, Group 2 (24 wk): CPT Class C (10-12)

Reporting group description:

LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class C (CPT score 10-12)

Reporting group title	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis

Reporting group description:

LDV/SOF+RBV tablets for 12 weeks in participants with Fibrosis Stage F0-F3

Reporting group title	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis

Reporting group description:

LDV/SOF+RBV 24 weeks in participants with Fibrosis Stage F0-F3

Reporting group title	Cohort B, Group 4 (12 wk): CPT Class A (5-6)

Reporting group description:

LDV/SOF+RBV tablets for 12 weeks in participants with CPT Class A (CPT score 5-6)

Reporting group title	Cohort B, Group 4 (24 wk): CPT Class A (5-6)

Reporting group description:

LDV/SOF+RBV for 24 weeks in participants with CPT Class A (CPT score 5-6)

Reporting group title	Cohort B, Group 5 (12 wk): CPT Class B (7-9)

Reporting group description:

LDV/SOF+RBV tablets for 12 weeks in participants with CPT Class B (CPT score 7-9)

Reporting group title	Cohort B, Group 5 (24 wk): CPT Class B (7-9)

Reporting group description:

LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class B (CPT score 7-9)

Reporting group title	Cohort B, Group 6 (12 wk): CPT Class C (10-12)

Reporting group description:

LDV/SOF+RBV tablets for 12 weeks in participants with CPT Class C (CPT score 10-12)

Reporting group title	Cohort B, Group 6 (24 wk): CPT Class C (10-12)

Reporting group description:

LDV/SOF+RBV tablets for 24 weeks in participants with CPT Class C (CPT score 10-12)

Reporting group title	Cohort B, Group 7 (12 wk): FCH

Reporting group description:

LDV/SOF+RBV tablets for 12 weeks in participants with fibrosing cholestatic hepatitis (FCH)

Reporting group title	Cohort B, Group 7 (24 wk): FCH

Reporting group description:

LDV/SOF+RBV tablets for 24 weeks in participants with FCH

Serious adverse events	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 28 (10.71%)	6 / 28 (21.43%)	13 / 25 (52.00%)
number of deaths (all causes)	1	1	5
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	0 / 25 (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
Lung neoplasm malignant			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 cell carcinoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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			
Hypotension			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Liver transplant rejection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal polyps			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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			
Post procedural haemorrhage			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia postoperative			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Congenital, familial and genetic disorders			
Left ventricle outflow tract obstruction			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 arrest			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 septal hypertrophy			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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			
Hepatic encephalopathy			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	2 / 25 (8.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 / 28 (0.00%)	1 / 28 (3.57%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 varices haemorrhage			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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	0 / 28 (0.00%)	1 / 28 (3.57%)	0 / 25 (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
Colitis			
subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	0 / 25 (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
Duodenal ulcer			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 varices haemorrhage			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	0 / 25 (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
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 ischaemia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised intraabdominal fluid collection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis haemorrhagic			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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			
Cholangitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	2 / 25 (8.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatorenal syndrome			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 / 28 (0.00%)	1 / 28 (3.57%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal impairment			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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			
Osteochondritis			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis staphylococcal			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	0 / 25 (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
Gastroenteritis viral			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus infection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal tuberculosis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 viral			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Streptococcal sepsis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
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	Cohort A, Group 2 (24 wk): CPT Class C (10-12)	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 26 (38.46%)	9 / 52 (17.31%)	5 / 49 (10.20%)
number of deaths (all causes)	4	2	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (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
Renal cell carcinoma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			

subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Liver transplant rejection			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (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
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			

subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (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
Acute respiratory failure			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (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
Hydrothorax			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal polyps			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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			
Post procedural haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia postoperative			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (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
Fall			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (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

Congenital, familial and genetic disorders			
Left ventricle outflow tract obstruction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (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
Atrial fibrillation			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (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
Bradycardia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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 arrest			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac septal hypertrophy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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			
Hepatic encephalopathy			

subjects affected / exposed	2 / 26 (7.69%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (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	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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 ulcer			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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 varices haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			

subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (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
Intestinal ischaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised intraabdominal fluid collection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis haemorrhagic			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			

subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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			
Cholangitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
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 failure			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (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
Portal vein thrombosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatorenal syndrome			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (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 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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			
Renal impairment			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			

subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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 colic			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (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
Renal failure acute			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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			
Osteochondritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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			
Pneumonia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (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
Sepsis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis staphylococcal			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			

subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal tuberculosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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 bacterial			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
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 tract infection viral			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			

subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (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
Hypoglycaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
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 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			

subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (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

Serious adverse events	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)	Cohort B, Group 5 (12 wk): CPT Class B (7-9)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 34 (8.82%)	7 / 33 (21.21%)	5 / 22 (22.73%)
number of deaths (all causes)	1	1	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Liver transplant rejection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal polyps			
subjects affected / exposed	1 / 34 (2.94%)	0 / 33 (0.00%)	0 / 22 (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
Pleuritic pain			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia postoperative			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Congenital, familial and genetic disorders			
Left ventricle outflow tract obstruction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac septal hypertrophy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 34 (2.94%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nervous system disorders			
Hepatic encephalopathy			

subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 34 (0.00%)	3 / 33 (9.09%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (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
Abdominal pain			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric varices haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised intraabdominal fluid collection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis haemorrhagic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 34 (2.94%)	0 / 33 (0.00%)	0 / 22 (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 haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatorenal syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal impairment			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Calculus ureteric			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 33 (0.00%)	0 / 22 (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
Hydronephrosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteochondritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis staphylococcal			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal tuberculosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis bacterial			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 23 (26.09%)	3 / 3 (100.00%)	2 / 5 (40.00%)
number of deaths (all causes)	0	1	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 cell carcinoma			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (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
Squamous cell carcinoma			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Hypotension			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			

subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Liver transplant rejection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	0 / 5 (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
Aspiration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal polyps			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Post procedural haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia postoperative			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (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
Wrist fracture			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Congenital, familial and genetic disorders			
Left ventricle outflow tract obstruction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 arrest			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 septal hypertrophy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Hepatic encephalopathy			

subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (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
Cerebral infarction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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	2 / 23 (8.70%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (4.35%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 varices haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 ulcer			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 varices haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			

subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (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
Inguinal hernia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 ischaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Localised intraabdominal fluid collection			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (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 haemorrhagic			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			

subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (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
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatorenal syndrome			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Renal impairment			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			

subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 colic			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	0 / 5 (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
Musculoskeletal and connective tissue disorders			
Osteochondritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Pneumonia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sepsis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	0 / 5 (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

Cellulitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis staphylococcal			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus infection			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	0 / 5 (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
Herpes zoster			

subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal tuberculosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 viral			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			

subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			

subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	1 / 2 (50.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein thrombosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Liver transplant rejection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal polyps			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood bilirubin increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Congenital, familial and genetic disorders			
Left ventricle outflow tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac septal hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Hepatic encephalopathy			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric varices haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated umbilical hernia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised intraabdominal fluid collection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatorenal syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus ureteric			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteochondritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis staphylococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophilus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			

subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Labyrinthitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal tuberculosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Cohort A, Group 1 (12 wk): CPT Class B (7-9)	Cohort A, Group 1 (24 wk): CPT Class B (7-9)	Cohort A, Group 2 (12 wk): CPT Class C (10-12)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 28 (89.29%)	25 / 28 (89.29%)	23 / 25 (92.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign pancreatic neoplasm			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Flushing			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	10 / 28 (35.71%)	9 / 28 (32.14%)	5 / 25 (20.00%)
occurrences (all)	10	10	6
Asthenia			
subjects affected / exposed	2 / 28 (7.14%)	2 / 28 (7.14%)	3 / 25 (12.00%)
occurrences (all)	2	2	3
Oedema peripheral			

subjects affected / exposed	2 / 28 (7.14%)	2 / 28 (7.14%)	1 / 25 (4.00%)
occurrences (all)	2	2	1
Pyrexia			
subjects affected / exposed	1 / 28 (3.57%)	2 / 28 (7.14%)	4 / 25 (16.00%)
occurrences (all)	1	3	5
Chest pain			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Oedema			
subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Feeling abnormal			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	1 / 28 (3.57%)	1 / 28 (3.57%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Peripheral swelling			
subjects affected / exposed	2 / 28 (7.14%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Social circumstances			
Eczema			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 28 (7.14%)	4 / 28 (14.29%)	4 / 25 (16.00%)
occurrences (all)	2	4	4
Dyspnoea			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	3 / 25 (12.00%)
occurrences (all)	0	0	4
Dyspnoea exertional			

subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	2 / 25 (8.00%)
occurrences (all)	0	1	2
Epistaxis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	2 / 28 (7.14%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 28 (3.57%)	4 / 28 (14.29%)	4 / 25 (16.00%)
occurrences (all)	1	4	4
Irritability			
subjects affected / exposed	2 / 28 (7.14%)	1 / 28 (3.57%)	1 / 25 (4.00%)
occurrences (all)	2	1	1
Sleep disorder			
subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Anxiety			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Agitation			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Investigations			
Haemoglobin decreased			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Blood sodium decreased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Blood pressure increased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 28 (0.00%)	2 / 28 (7.14%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Fall			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Muscle strain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	8 / 28 (28.57%)	7 / 28 (25.00%)	7 / 25 (28.00%)
occurrences (all)	9	9	8
Dizziness			
subjects affected / exposed	4 / 28 (14.29%)	3 / 28 (10.71%)	1 / 25 (4.00%)
occurrences (all)	4	3	1
Lethargy			
subjects affected / exposed	2 / 28 (7.14%)	0 / 28 (0.00%)	3 / 25 (12.00%)
occurrences (all)	3	0	3
Hepatic encephalopathy			
subjects affected / exposed	0 / 28 (0.00%)	11 / 28 (39.29%)	2 / 25 (8.00%)
occurrences (all)	0	1	2
Tremor			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Somnolence			

subjects affected / exposed	2 / 28 (7.14%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	2	0	1
Syncope			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 28 (3.57%)	3 / 28 (10.71%)	5 / 25 (20.00%)
occurrences (all)	1	3	6
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 28 (0.00%)	3 / 28 (10.71%)	0 / 25 (0.00%)
occurrences (all)	0	3	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Eyelid cyst			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Ocular icterus			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pterygium			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	5 / 28 (17.86%)	6 / 28 (21.43%)	3 / 25 (12.00%)
occurrences (all)	8	7	4
Nausea			
subjects affected / exposed	6 / 28 (21.43%)	4 / 28 (14.29%)	4 / 25 (16.00%)
occurrences (all)	6	4	4
Vomiting			
subjects affected / exposed	2 / 28 (7.14%)	2 / 28 (7.14%)	6 / 25 (24.00%)
occurrences (all)	3	2	9
Abdominal pain			

subjects affected / exposed	2 / 28 (7.14%)	3 / 28 (10.71%)	3 / 25 (12.00%)
occurrences (all)	2	3	4
Dyspepsia			
subjects affected / exposed	0 / 28 (0.00%)	3 / 28 (10.71%)	0 / 25 (0.00%)
occurrences (all)	0	3	0
Constipation			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	3 / 25 (12.00%)
occurrences (all)	0	0	3
Abdominal pain upper			
subjects affected / exposed	0 / 28 (0.00%)	2 / 28 (7.14%)	3 / 25 (12.00%)
occurrences (all)	0	2	4
Ascites			
subjects affected / exposed	0 / 28 (0.00%)	3 / 28 (10.71%)	1 / 25 (4.00%)
occurrences (all)	0	3	1
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 28 (3.57%)	1 / 28 (3.57%)	1 / 25 (4.00%)
occurrences (all)	1	1	1
Abdominal discomfort			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	1 / 28 (3.57%)	1 / 28 (3.57%)	1 / 25 (4.00%)
occurrences (all)	1	1	1
Dry mouth			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 28 (0.00%)	2 / 28 (7.14%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Abdominal pain lower			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	0 / 28 (0.00%)	2 / 28 (7.14%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Hyperbilirubinaemia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	5 / 28 (17.86%)	8 / 28 (28.57%)	3 / 25 (12.00%)
occurrences (all)	5	9	3
Rash			
subjects affected / exposed	0 / 28 (0.00%)	4 / 28 (14.29%)	2 / 25 (8.00%)
occurrences (all)	0	4	2
Dry skin			
subjects affected / exposed	1 / 28 (3.57%)	1 / 28 (3.57%)	1 / 25 (4.00%)
occurrences (all)	1	1	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	2 / 28 (7.14%)	5 / 28 (17.86%)	5 / 25 (20.00%)
occurrences (all)	3	5	5
Back pain			
subjects affected / exposed	1 / 28 (3.57%)	2 / 28 (7.14%)	2 / 25 (8.00%)
occurrences (all)	1	2	2
Myalgia			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Arthralgia			

subjects affected / exposed	1 / 28 (3.57%)	2 / 28 (7.14%)	1 / 25 (4.00%)
occurrences (all)	1	2	1
Pain in extremity			
subjects affected / exposed	1 / 28 (3.57%)	1 / 28 (3.57%)	1 / 25 (4.00%)
occurrences (all)	1	1	1
Musculoskeletal pain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 28 (7.14%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	2	0	1
Urinary tract infection			
subjects affected / exposed	1 / 28 (3.57%)	1 / 28 (3.57%)	3 / 25 (12.00%)
occurrences (all)	1	1	5
Influenza			
subjects affected / exposed	0 / 28 (0.00%)	2 / 28 (7.14%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Oral herpes			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	3 / 28 (10.71%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	3	0	1

Herpes zoster			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Puncture site infection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 28 (3.57%)	1 / 28 (3.57%)	4 / 25 (16.00%)
occurrences (all)	1	1	4
Hyponatraemia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Hyperkalaemia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Diabetes mellitus			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Gout			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort A, Group 2 (24 wk): CPT Class C (10-12)	Cohort B, Group 3 (12 wk): F0-F3 Fibrosis	Cohort B, Group 3 (24 wk): F0-F3 Fibrosis

Total subjects affected by non-serious adverse events subjects affected / exposed	23 / 26 (88.46%)	49 / 52 (94.23%)	48 / 49 (97.96%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Benign pancreatic neoplasm subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 52 (0.00%) 0	0 / 49 (0.00%) 0
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	2 / 52 (3.85%) 2	1 / 49 (2.04%) 1
Haematoma subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 52 (0.00%) 0	3 / 49 (6.12%) 3
Hot flush subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 52 (0.00%) 0	1 / 49 (2.04%) 1
Flushing subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 52 (0.00%) 0	0 / 49 (0.00%) 0
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	8 / 26 (30.77%) 8	22 / 52 (42.31%) 22	20 / 49 (40.82%) 21
Asthenia subjects affected / exposed occurrences (all)	4 / 26 (15.38%) 4	4 / 52 (7.69%) 4	4 / 49 (8.16%) 4
Oedema peripheral subjects affected / exposed occurrences (all)	7 / 26 (26.92%) 7	0 / 52 (0.00%) 0	0 / 49 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	3 / 26 (11.54%) 3	1 / 52 (1.92%) 1	2 / 49 (4.08%) 2
Chest pain subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 52 (0.00%) 0	2 / 49 (4.08%) 2
Oedema			

subjects affected / exposed	3 / 26 (11.54%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	3	0	0
Feeling abnormal			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	2
Influenza like illness			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	1 / 49 (2.04%)
occurrences (all)	0	1	1
Social circumstances			
Eczema			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	6 / 49 (12.24%)
occurrences (all)	0	1	6
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 26 (15.38%)	5 / 52 (9.62%)	8 / 49 (16.33%)
occurrences (all)	4	6	10
Dyspnoea			
subjects affected / exposed	3 / 26 (11.54%)	9 / 52 (17.31%)	4 / 49 (8.16%)
occurrences (all)	4	10	4
Dyspnoea exertional			
subjects affected / exposed	2 / 26 (7.69%)	5 / 52 (9.62%)	3 / 49 (6.12%)
occurrences (all)	2	5	3
Pleural effusion			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	2	0	0
Epistaxis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences (all)	1	0	1
Oropharyngeal pain			

subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	3 / 49 (6.12%)
occurrences (all)	0	0	4
Productive cough			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	4 / 26 (15.38%)	8 / 52 (15.38%)	10 / 49 (20.41%)
occurrences (all)	5	8	10
Irritability			
subjects affected / exposed	1 / 26 (3.85%)	2 / 52 (3.85%)	3 / 49 (6.12%)
occurrences (all)	1	2	3
Sleep disorder			
subjects affected / exposed	1 / 26 (3.85%)	4 / 52 (7.69%)	0 / 49 (0.00%)
occurrences (all)	1	5	0
Anxiety			
subjects affected / exposed	1 / 26 (3.85%)	2 / 52 (3.85%)	1 / 49 (2.04%)
occurrences (all)	1	2	1
Depression			
subjects affected / exposed	1 / 26 (3.85%)	1 / 52 (1.92%)	1 / 49 (2.04%)
occurrences (all)	1	1	1
Agitation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Investigations			
Haemoglobin decreased			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	1 / 49 (2.04%)
occurrences (all)	0	1	1
Blood sodium decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 26 (7.69%)	12 / 52 (23.08%)	14 / 49 (28.57%)
occurrences (all)	2	13	15
Dizziness			
subjects affected / exposed	2 / 26 (7.69%)	7 / 52 (13.46%)	5 / 49 (10.20%)
occurrences (all)	2	8	5
Lethargy			
subjects affected / exposed	3 / 26 (11.54%)	1 / 52 (1.92%)	3 / 49 (6.12%)
occurrences (all)	4	1	4
Hepatic encephalopathy			
subjects affected / exposed	4 / 26 (15.38%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	5	0	0
Tremor			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	4 / 49 (8.16%)
occurrences (all)	1	0	5
Somnolence			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 26 (30.77%)	21 / 52 (40.38%)	27 / 49 (55.10%)
occurrences (all)	12	22	31
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Eyelid cyst			
subjects affected / exposed	2 / 26 (7.69%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	2	0	0
Ocular icterus			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Pterygium			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 26 (11.54%)	12 / 52 (23.08%)	11 / 49 (22.45%)
occurrences (all)	5	14	14
Nausea			
subjects affected / exposed	5 / 26 (19.23%)	13 / 52 (25.00%)	6 / 49 (12.24%)
occurrences (all)	5	14	6
Vomiting			
subjects affected / exposed	3 / 26 (11.54%)	5 / 52 (9.62%)	3 / 49 (6.12%)
occurrences (all)	3	11	3
Abdominal pain			
subjects affected / exposed	1 / 26 (3.85%)	4 / 52 (7.69%)	5 / 49 (10.20%)
occurrences (all)	1	4	5
Dyspepsia			
subjects affected / exposed	1 / 26 (3.85%)	5 / 52 (9.62%)	4 / 49 (8.16%)
occurrences (all)	1	5	4
Constipation			
subjects affected / exposed	1 / 26 (3.85%)	2 / 52 (3.85%)	5 / 49 (10.20%)
occurrences (all)	1	2	5
Abdominal pain upper			

subjects affected / exposed	0 / 26 (0.00%)	2 / 52 (3.85%)	4 / 49 (8.16%)
occurrences (all)	0	2	4
Ascites			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 26 (3.85%)	1 / 52 (1.92%)	0 / 49 (0.00%)
occurrences (all)	1	1	0
Abdominal discomfort			
subjects affected / exposed	2 / 26 (7.69%)	2 / 52 (3.85%)	1 / 49 (2.04%)
occurrences (all)	2	2	1
Abdominal distension			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	2
Dry mouth			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	2
Flatulence			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 26 (3.85%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	1 / 26 (3.85%)	2 / 52 (3.85%)	2 / 49 (4.08%)
occurrences (all)	1	2	2

Hyperbilirubinaemia			
subjects affected / exposed	2 / 26 (7.69%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences (all)	2	0	1
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	4 / 26 (15.38%)	5 / 52 (9.62%)	6 / 49 (12.24%)
occurrences (all)	5	8	6
Rash			
subjects affected / exposed	2 / 26 (7.69%)	4 / 52 (7.69%)	3 / 49 (6.12%)
occurrences (all)	2	4	4
Dry skin			
subjects affected / exposed	0 / 26 (0.00%)	2 / 52 (3.85%)	3 / 49 (6.12%)
occurrences (all)	0	2	3
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	4 / 26 (15.38%)	2 / 52 (3.85%)	3 / 49 (6.12%)
occurrences (all)	4	2	3
Back pain			
subjects affected / exposed	1 / 26 (3.85%)	5 / 52 (9.62%)	4 / 49 (8.16%)
occurrences (all)	1	5	4
Myalgia			
subjects affected / exposed	2 / 26 (7.69%)	5 / 52 (9.62%)	4 / 49 (8.16%)
occurrences (all)	2	5	5
Arthralgia			
subjects affected / exposed	1 / 26 (3.85%)	2 / 52 (3.85%)	1 / 49 (2.04%)
occurrences (all)	1	2	1
Pain in extremity			
subjects affected / exposed	2 / 26 (7.69%)	1 / 52 (1.92%)	3 / 49 (6.12%)
occurrences (all)	2	1	3
Musculoskeletal pain			
subjects affected / exposed	0 / 26 (0.00%)	1 / 52 (1.92%)	2 / 49 (4.08%)
occurrences (all)	0	1	2
Musculoskeletal chest pain			

subjects affected / exposed	0 / 26 (0.00%)	3 / 52 (5.77%)	0 / 49 (0.00%)
occurrences (all)	0	3	0
Flank pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 26 (0.00%)	4 / 52 (7.69%)	5 / 49 (10.20%)
occurrences (all)	0	4	6
Urinary tract infection			
subjects affected / exposed	2 / 26 (7.69%)	2 / 52 (3.85%)	1 / 49 (2.04%)
occurrences (all)	2	2	1
Influenza			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	4 / 49 (8.16%)
occurrences (all)	0	0	4
Oral herpes			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	4 / 49 (8.16%)
occurrences (all)	0	0	4
Sinusitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Herpes zoster			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	2 / 26 (7.69%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	2	0	0
Pharyngitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Puncture site infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 26 (3.85%)	2 / 52 (3.85%)	5 / 49 (10.20%)
occurrences (all)	1	2	5
Hyponatraemia			
subjects affected / exposed	4 / 26 (15.38%)	1 / 52 (1.92%)	0 / 49 (0.00%)
occurrences (all)	4	1	0
Hyperkalaemia			
subjects affected / exposed	2 / 26 (7.69%)	1 / 52 (1.92%)	0 / 49 (0.00%)
occurrences (all)	2	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	3 / 26 (11.54%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	3	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 26 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort B, Group 4 (12 wk): CPT Class A (5-6)	Cohort B, Group 4 (24 wk): CPT Class A (5-6)	Cohort B, Group 5 (12 wk): CPT Class B (7-9)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 34 (79.41%)	30 / 33 (90.91%)	20 / 22 (90.91%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign pancreatic neoplasm			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			

subjects affected / exposed	1 / 34 (2.94%)	0 / 33 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	2
Haematoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 34 (23.53%)	11 / 33 (33.33%)	7 / 22 (31.82%)
occurrences (all)	9	11	8
Asthenia			
subjects affected / exposed	5 / 34 (14.71%)	7 / 33 (21.21%)	1 / 22 (4.55%)
occurrences (all)	5	9	1
Oedema peripheral			
subjects affected / exposed	3 / 34 (8.82%)	2 / 33 (6.06%)	2 / 22 (9.09%)
occurrences (all)	3	3	3
Pyrexia			
subjects affected / exposed	1 / 34 (2.94%)	2 / 33 (6.06%)	1 / 22 (4.55%)
occurrences (all)	1	3	1
Chest pain			
subjects affected / exposed	2 / 34 (5.88%)	2 / 33 (6.06%)	0 / 22 (0.00%)
occurrences (all)	2	3	0
Oedema			
subjects affected / exposed	1 / 34 (2.94%)	1 / 33 (3.03%)	1 / 22 (4.55%)
occurrences (all)	1	1	1
Feeling abnormal			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Eczema			
subjects affected / exposed	0 / 34 (0.00%)	3 / 33 (9.09%)	0 / 22 (0.00%)
occurrences (all)	0	3	0
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 34 (11.76%)	7 / 33 (21.21%)	3 / 22 (13.64%)
occurrences (all)	4	7	3
Dyspnoea			
subjects affected / exposed	5 / 34 (14.71%)	3 / 33 (9.09%)	2 / 22 (9.09%)
occurrences (all)	5	4	2
Dyspnoea exertional			
subjects affected / exposed	1 / 34 (2.94%)	2 / 33 (6.06%)	1 / 22 (4.55%)
occurrences (all)	1	2	1
Pleural effusion			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	2 / 22 (9.09%)
occurrences (all)	0	1	2
Epistaxis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Psychiatric disorders			

Insomnia			
subjects affected / exposed	4 / 34 (11.76%)	3 / 33 (9.09%)	2 / 22 (9.09%)
occurrences (all)	4	5	2
Irritability			
subjects affected / exposed	2 / 34 (5.88%)	3 / 33 (9.09%)	0 / 22 (0.00%)
occurrences (all)	2	3	0
Sleep disorder			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	1 / 34 (2.94%)	1 / 33 (3.03%)	1 / 22 (4.55%)
occurrences (all)	1	1	1
Depression			
subjects affected / exposed	1 / 34 (2.94%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Agitation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Investigations			
Haemoglobin decreased			
subjects affected / exposed	2 / 34 (5.88%)	3 / 33 (9.09%)	1 / 22 (4.55%)
occurrences (all)	2	3	1
Blood sodium decreased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 34 (2.94%)	2 / 33 (6.06%)	0 / 22 (0.00%)
occurrences (all)	1	2	0
Fall			
subjects affected / exposed	0 / 34 (0.00%)	4 / 33 (12.12%)	0 / 22 (0.00%)
occurrences (all)	0	4	0
Muscle strain			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 34 (17.65%)	9 / 33 (27.27%)	2 / 22 (9.09%)
occurrences (all)	6	9	2
Dizziness			
subjects affected / exposed	3 / 34 (8.82%)	1 / 33 (3.03%)	2 / 22 (9.09%)
occurrences (all)	3	1	2
Lethargy			
subjects affected / exposed	1 / 34 (2.94%)	3 / 33 (9.09%)	1 / 22 (4.55%)
occurrences (all)	1	4	1
Hepatic encephalopathy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 34 (2.94%)	1 / 33 (3.03%)	1 / 22 (4.55%)
occurrences (all)	1	1	1
Somnolence			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 34 (2.94%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	10 / 34 (29.41%)	15 / 33 (45.45%)	6 / 22 (27.27%)
occurrences (all)	10	15	6
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Vision blurred			
subjects affected / exposed	1 / 34 (2.94%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Eyelid cyst			

subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ocular icterus			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pterygium			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	5 / 34 (14.71%)	1 / 33 (3.03%)	2 / 22 (9.09%)
occurrences (all)	5	13	2
Nausea			
subjects affected / exposed	5 / 34 (14.71%)	10 / 33 (30.30%)	6 / 22 (27.27%)
occurrences (all)	5	12	6
Vomiting			
subjects affected / exposed	4 / 34 (11.76%)	4 / 33 (12.12%)	3 / 22 (13.64%)
occurrences (all)	4	5	3
Abdominal pain			
subjects affected / exposed	3 / 34 (8.82%)	4 / 33 (12.12%)	1 / 22 (4.55%)
occurrences (all)	3	4	1
Dyspepsia			
subjects affected / exposed	1 / 34 (2.94%)	4 / 33 (12.12%)	0 / 22 (0.00%)
occurrences (all)	1	4	0
Constipation			
subjects affected / exposed	2 / 34 (5.88%)	2 / 33 (6.06%)	1 / 22 (4.55%)
occurrences (all)	2	2	2
Abdominal pain upper			
subjects affected / exposed	3 / 34 (8.82%)	1 / 33 (3.03%)	1 / 22 (4.55%)
occurrences (all)	3	1	1
Ascites			
subjects affected / exposed	0 / 34 (0.00%)	3 / 33 (9.09%)	1 / 22 (4.55%)
occurrences (all)	0	3	1
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 34 (2.94%)	1 / 33 (3.03%)	2 / 22 (9.09%)
occurrences (all)	1	1	2

Abdominal discomfort			
subjects affected / exposed	2 / 34 (5.88%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Abdominal distension			
subjects affected / exposed	1 / 34 (2.94%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	1 / 34 (2.94%)	2 / 33 (6.06%)	1 / 22 (4.55%)
occurrences (all)	1	2	1
Gastritis			
subjects affected / exposed	0 / 34 (0.00%)	2 / 33 (6.06%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Flatulence			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	3 / 34 (8.82%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences (all)	3	1	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	4 / 34 (11.76%)	7 / 33 (21.21%)	2 / 22 (9.09%)
occurrences (all)	4	8	2
Rash			

subjects affected / exposed	4 / 34 (11.76%)	1 / 33 (3.03%)	2 / 22 (9.09%)
occurrences (all)	4	1	2
Dry skin			
subjects affected / exposed	0 / 34 (0.00%)	2 / 33 (6.06%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	1 / 34 (2.94%)	3 / 33 (9.09%)	0 / 22 (0.00%)
occurrences (all)	2	3	0
Back pain			
subjects affected / exposed	2 / 34 (5.88%)	3 / 33 (9.09%)	2 / 22 (9.09%)
occurrences (all)	2	3	2
Myalgia			
subjects affected / exposed	0 / 34 (0.00%)	4 / 33 (12.12%)	1 / 22 (4.55%)
occurrences (all)	0	4	1
Arthralgia			
subjects affected / exposed	1 / 34 (2.94%)	4 / 33 (12.12%)	0 / 22 (0.00%)
occurrences (all)	1	5	0
Pain in extremity			
subjects affected / exposed	0 / 34 (0.00%)	2 / 33 (6.06%)	1 / 22 (4.55%)
occurrences (all)	0	2	1
Musculoskeletal pain			
subjects affected / exposed	0 / 34 (0.00%)	2 / 33 (6.06%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	0 / 34 (0.00%)	2 / 33 (6.06%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Osteopenia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 34 (5.88%)	5 / 33 (15.15%)	1 / 22 (4.55%)
occurrences (all)	2	5	1
Urinary tract infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	2 / 34 (5.88%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences (all)	2	1	0
Tooth infection			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Puncture site infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	3 / 34 (8.82%)	4 / 33 (12.12%)	2 / 22 (9.09%)
occurrences (all)	3	4	2
Hyponatraemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Hypoglycaemia			
subjects affected / exposed	2 / 34 (5.88%)	1 / 33 (3.03%)	0 / 22 (0.00%)
occurrences (all)	2	1	0
Hypokalaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Gout			
subjects affected / exposed	0 / 34 (0.00%)	2 / 33 (6.06%)	0 / 22 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Cohort B, Group 5 (24 wk): CPT Class B (7-9)	Cohort B, Group 6 (12 wk): CPT Class C (10-12)	Cohort B, Group 6 (24 wk): CPT Class C (10-12)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 23 (86.96%)	3 / 3 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign pancreatic neoplasm			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hot flush			

subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Flushing			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	9 / 23 (39.13%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	9	1	1
Asthenia			
subjects affected / exposed	4 / 23 (17.39%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	4	1	1
Oedema peripheral			
subjects affected / exposed	2 / 23 (8.70%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Pyrexia			
subjects affected / exposed	2 / 23 (8.70%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Chest pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Social circumstances			

Eczema			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	2 / 23 (8.70%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 23 (17.39%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	5	0	0
Dyspnoea			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	2 / 23 (8.70%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	4 / 23 (17.39%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	4	1	0
Irritability			
subjects affected / exposed	2 / 23 (8.70%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0

Sleep disorder			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	2 / 23 (8.70%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Agitation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Haemoglobin decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Muscle strain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 23 (30.43%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	8	0	1

Dizziness			
subjects affected / exposed	2 / 23 (8.70%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Lethargy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatic encephalopathy			
subjects affected / exposed	1 / 23 (4.35%)	2 / 3 (66.67%)	2 / 5 (40.00%)
occurrences (all)	1	3	2
Tremor			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	2 / 23 (8.70%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Syncope			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	12 / 23 (52.17%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	14	1	1
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Eyelid cyst			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ocular icterus			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pterygium			

subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 23 (13.04%)	1 / 3 (33.33%)	2 / 5 (40.00%)
occurrences (all)	8	1	2
Nausea			
subjects affected / exposed	3 / 23 (13.04%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Vomiting			
subjects affected / exposed	4 / 23 (17.39%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	5	0	0
Abdominal pain			
subjects affected / exposed	2 / 23 (8.70%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Dyspepsia			
subjects affected / exposed	2 / 23 (8.70%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Constipation			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	2 / 23 (8.70%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Abdominal discomfort			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	2 / 23 (8.70%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0

Dry mouth			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gait disturbance			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	1 / 23 (4.35%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	2 / 23 (8.70%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			

subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 23 (4.35%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Myalgia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Arthralgia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 23 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Nasopharyngitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Puncture site infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			

subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 23 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort B, Group 7 (12 wk): FCH	Cohort B, Group 7 (24 wk): FCH	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	2 / 2 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign pancreatic neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Feeling abnormal			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Social circumstances			
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Irritability			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Depression			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Investigations			
Haemoglobin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blood sodium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blood pressure increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Muscle strain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Dizziness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hepatic encephalopathy			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Syncope			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 2 (50.00%)	
occurrences (all)	2	1	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Eyelid cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Ocular icterus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pterygium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Nausea			

subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Flatulence			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Rash			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Back pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Osteopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Puncture site infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Diabetes mellitus			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Gout			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 January 2014	1) An equivalent study conducted in the US (GS-US-337-0123) showed that Cohort B, Group 7 was challenging to enroll based on the current exclusion requirements for hematology and chemistry parameters; specifically alanine aminotransferase (ALT), aspartate aminotransferase (AST), or alkaline phosphatase ≥ 10 × the upper limit of normal (ULN). These parameters were no longer used to determine eligibility for Group 7. In addition, the stopping rules for individual subjects were clarified for Cohort B, Group 7; 2) Clarification was added for RBV dose reductions for renal impairment; 3) Clarification was added that the Ampliprep® assay was used for HCV RNA quantitation and used plasma instead of serum.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

There were no limitations affecting the analysis or results.

Notes: