Clinical trial results:
A multi-centre 3-year follow-up study to assess the durability of sustained virologic response in alisporivir treated chronic hepatitis C patients

Summary

EudraCT number	2011-006131-38
Trial protocol	ES HU GB PL IT DE
Global end of trial date	22 May 2015

Results information

Result version number	v1 (current)
This version publication date	26 May 2016
First version publication date	26 May 2016

Trial information

Trial identification

Sponsor protocol code	CDEB025A2312

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	CH 4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,

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	22 May 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 May 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the durability of sustained virologic response after SVR24 has been achieved in patients treated with alisporivir in a Novartis-sponsored chronic Hepatitis C study.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 April 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 3
Country: Number of subjects enrolled	Australia: 20
Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	Canada: 13
Country: Number of subjects enrolled	Hong Kong: 13
Country: Number of subjects enrolled	India: 32
Country: Number of subjects enrolled	Korea, Republic of: 51
Country: Number of subjects enrolled	Mexico: 8
Country: Number of subjects enrolled	Romania: 62
Country: Number of subjects enrolled	Russian Federation: 19
Country: Number of subjects enrolled	Taiwan: 76
Country: Number of subjects enrolled	Thailand: 76
Country: Number of subjects enrolled	Turkey: 14
Country: Number of subjects enrolled	United States: 31
Country: Number of subjects enrolled	Vietnam: 41
Country: Number of subjects enrolled	Poland: 65
Country: Number of subjects enrolled	Spain: 25

Country: Number of subjects enrolled	United Kingdom: 21
Country: Number of subjects enrolled	France: 13
Country: Number of subjects enrolled	Germany: 43
Country: Number of subjects enrolled	Hungary: 42
Country: Number of subjects enrolled	Italy: 53
Worldwide total number of subjects	723
EEA total number of subjects	326

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)	688
From 65 to 84 years	35
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study was a follow-up study where patients who achieved Sustained virologic response (SVR24) with alisporivir treatment were enrolled into this study from various Novartis studies (called feeder studies). These patients were followed up for about 2 years from last dose of study treatment, with a maximum of three visits in this study.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	From Study 2210

Arm description: -

Arm type	No intervention
Investigational medicinal product name	No intervention
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Not mentioned

Dosage and administration details:

There was no investigational treatment given to patients enrolled in this study.

Arm title	From Study 2301

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	From Study 2211 IFN-free

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	From Study 2211 Overall

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	From Study 2210	From Study 2301	From Study 2211 IFN-free
Started	164	397	54
Completed	150	354	47
Not completed	14	43	7
Physician decision	1	2	-
Study terminated by sponsor	-	3	-
Lost to follow-up	6	18	4
Subject/guardian decision	4	3	2
Protocol deviation	3	17	1

Number of subjects in period 1	From Study 2211 Overall
Started	162
Completed	139
Not completed	23
Physician decision	-
Study terminated by sponsor	-
Lost to follow-up	16
Subject/guardian decision	5
Protocol deviation	2

Baseline characteristics

Reporting groups	
Reporting group title	From Study 2210
Reporting group description: -	
Reporting group title	From Study 2301
Reporting group description: -	
Reporting group title	From Study 2211 IFN-free
Reporting group description: -	
Reporting group title	From Study 2211 Overall
Reporting group description: -	

Reporting group values	From Study 2210	From Study 2301	From Study 2211 IFN-free
Number of subjects	164	397	54
Age categorical Units: Subjects			
Adults (18-64 years)	152	376	54
From 65-84 years	12	21	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	52.5	46.4	40.9
standard deviation	± 9.89	± 11.7	± 10.98
Gender categorical Units: Subjects			
Female	58	182	15
Male	106	215	39

Reporting group values	From Study 2211 Overall	Total	
Number of subjects	162	723	
Age categorical Units: Subjects			
Adults (18-64 years)	160	688	
From 65-84 years	2	35	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	43.7		
standard deviation	± 10.89	-	
Gender categorical Units: Subjects			
Female	61	301	
Male	101	422	

End points

End points reporting groups

Reporting group title	From Study 2210
Reporting group description: -	
Reporting group title	From Study 2301
Reporting group description: -	
Reporting group title	From Study 2211 IFN-free
Reporting group description: -	
Reporting group title	From Study 2211 Overall
Reporting group description: -	

Primary: Percentage of patients maintaining HCV RNA load below LOQ (Full Analysis Set)

End point title	Percentage of patients maintaining HCV RNA load below LOQ (Full Analysis Set)[1]
End point description:	
End point type	Primary
End point timeframe:	
Baseline through Week 48	

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 analyses have been performed for this primary end point.

End point values	From Study 2210	From Study 2301	From Study 2211 IFN-free	From Study 2211 Overall
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	161[2]	383[3]	53[4]	160[5]
Units: percent				
number (not applicable)				
Week 1	96.7	99.5	100	100
Week 24	100	100	98	99.3
Week 48	100	99.7	100	100

Notes:

[2] - Full Analysis Set- all patients who enrolled into this study and had at least one HCV RNA assessment
[3] - Full Analysis Set- all patients who enrolled into this study and had at least one HCV RNA assessment
[4] - Full Analysis Set- all patients who enrolled into this study and had at least one HCV RNA assessment
[5] - Full Analysis Set- all patients who enrolled into this study and had at least one HCV RNA assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of patients with normal Alanine-aminotransferase (ALT)

End point title	Percentage of patients with normal Alanine-aminotransferase (ALT)

End point description:

End point type	Secondary

End point timeframe:

Week 48

End point values	From Study 2210	From Study 2301	From Study 2211 IFN-free	From Study 2211 Overall
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	161[6]	383[7]	53[8]	160[9]
Units: percent				
number (not applicable)				
Week 1	88.8	94	96	95.5
Week 24	84	93.9	82	89.4
Week 48	88.2	91.5	87.2	91.5

Notes:

[6] - Full Analysis Set- all patients who enrolled into this study and had at least one HCV RNA assessment

[7] - Full Analysis Set- all patients who enrolled into this study and had at least one HCV RNA assessment

[8] - Full Analysis Set- all patients who enrolled into this study and had at least one HCV RNA assessment

[9] - Full Analysis Set- all patients who enrolled into this study and had at least one HCV RNA assessment

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	From Study 2210
Reporting group description:	
From Study 2210	
Reporting group title	From Study 2301
Reporting group description:	
From Study 2301	
Reporting group title	From Study 2211 IFN-free
Reporting group description:	
From Study 2211 IFN-free	
Reporting group title	From Study 2211 Overall
Reporting group description:	
From Study 2211 Overall	

Serious adverse events	From Study 2210	From Study 2301	From Study 2211 IFN-free
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 164 (4.27%)	8 / 397 (2.02%)	1 / 54 (1.85%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BLADDER CANCER			
subjects affected / exposed	1 / 164 (0.61%)	0 / 397 (0.00%)	0 / 54 (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
BREAST CANCER IN SITU			
subjects affected / exposed	0 / 164 (0.00%)	0 / 397 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLESTEATOMA			

subjects affected / exposed	0 / 164 (0.00%)	1 / 397 (0.25%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC CANCER			
subjects affected / exposed	0 / 164 (0.00%)	1 / 397 (0.25%)	0 / 54 (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
HEPATOCELLULAR CARCINOMA			
subjects affected / exposed	1 / 164 (0.61%)	0 / 397 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ABDOMINAL WOUND DEHISCENCE			
subjects affected / exposed	0 / 164 (0.00%)	1 / 397 (0.25%)	0 / 54 (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
CONCUSSION			
subjects affected / exposed	0 / 164 (0.00%)	0 / 397 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONTUSION			
subjects affected / exposed	0 / 164 (0.00%)	0 / 397 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FIBULA FRACTURE			
subjects affected / exposed	1 / 164 (0.61%)	0 / 397 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
MYOCARDIAL INFARCTION			
subjects affected / exposed	1 / 164 (0.61%)	0 / 397 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
HYPOCHROMIC ANAEMIA			
subjects affected / exposed	1 / 164 (0.61%)	0 / 397 (0.00%)	0 / 54 (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
Gastrointestinal disorders			
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	1 / 164 (0.61%)	0 / 397 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	0 / 164 (0.00%)	1 / 397 (0.25%)	0 / 54 (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
Psychiatric disorders			
ALCOHOL ABUSE			
subjects affected / exposed	0 / 164 (0.00%)	1 / 397 (0.25%)	0 / 54 (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
SUICIDAL IDEATION			
subjects affected / exposed	0 / 164 (0.00%)	0 / 397 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
COLLAGEN DISORDER			
subjects affected / exposed	1 / 164 (0.61%)	0 / 397 (0.00%)	0 / 54 (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
ROTATOR CUFF SYNDROME			
subjects affected / exposed	0 / 164 (0.00%)	1 / 397 (0.25%)	0 / 54 (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			
HERPES SIMPLEX MENINGITIS			

subjects affected / exposed	0 / 164 (0.00%)	1 / 397 (0.25%)	0 / 54 (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
MENINGITIS VIRAL			
subjects affected / exposed	0 / 164 (0.00%)	1 / 397 (0.25%)	0 / 54 (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
OSTEOMYELITIS ACUTE			
subjects affected / exposed	0 / 164 (0.00%)	1 / 397 (0.25%)	0 / 54 (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
OTITIS MEDIA CHRONIC			
subjects affected / exposed	0 / 164 (0.00%)	1 / 397 (0.25%)	0 / 54 (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
PNEUMOCOCCAL SEPSIS			
subjects affected / exposed	1 / 164 (0.61%)	0 / 397 (0.00%)	0 / 54 (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
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 164 (0.00%)	1 / 397 (0.25%)	0 / 54 (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

Serious adverse events	From Study 2211 Overall		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 162 (1.85%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BLADDER CANCER			

subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
BREAST CANCER IN SITU				
subjects affected / exposed	1 / 162 (0.62%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
CHOLESTEATOMA				
subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HEPATIC CANCER				
subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HEPATOCELLULAR CARCINOMA				
subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
ABDOMINAL WOUND DEHISCENCE				
subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
CONCUSSION				
subjects affected / exposed	1 / 162 (0.62%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
CONTUSION				
subjects affected / exposed	1 / 162 (0.62%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
FIBULA FRACTURE				

subjects affected / exposed	0 / 162 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 162 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
HYPOCHROMIC ANAEMIA			
subjects affected / exposed	0 / 162 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 162 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	0 / 162 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
ALCOHOL ABUSE			
subjects affected / exposed	0 / 162 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
SUICIDAL IDEATION			
subjects affected / exposed	1 / 162 (0.62%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
COLLAGEN DISORDER			

subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ROTATOR CUFF SYNDROME				
subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
HERPES SIMPLEX MENINGITIS				
subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
MENINGITIS VIRAL				
subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
OSTEOMYELITIS ACUTE				
subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
OTITIS MEDIA CHRONIC				
subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PNEUMOCOCCAL SEPSIS				
subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
VIRAL UPPER RESPIRATORY TRACT INFECTION				
subjects affected / exposed	0 / 162 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	From Study 2210	From Study 2301	From Study 2211 IFN-free
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 164 (8.54%)	12 / 397 (3.02%)	5 / 54 (9.26%)
Nervous system disorders			
HEADACHE			
subjects affected / exposed	4 / 164 (2.44%)	1 / 397 (0.25%)	0 / 54 (0.00%)
occurrences (all)	4	1	0
Gastrointestinal disorders			
FLATULENCE			
subjects affected / exposed	1 / 164 (0.61%)	0 / 397 (0.00%)	2 / 54 (3.70%)
occurrences (all)	1	0	2
Hepatobiliary disorders			
HEPATIC STEATOSIS			
subjects affected / exposed	4 / 164 (2.44%)	7 / 397 (1.76%)	1 / 54 (1.85%)
occurrences (all)	4	7	1
HEPATOMEGALY			
subjects affected / exposed	4 / 164 (2.44%)	1 / 397 (0.25%)	0 / 54 (0.00%)
occurrences (all)	4	1	0
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	1 / 164 (0.61%)	0 / 397 (0.00%)	2 / 54 (3.70%)
occurrences (all)	1	0	2
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	4 / 164 (2.44%)	4 / 397 (1.01%)	1 / 54 (1.85%)
occurrences (all)	4	4	1

Non-serious adverse events	From Study 2211 Overall		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 162 (6.79%)		
Nervous system disorders			
HEADACHE			
subjects affected / exposed	0 / 162 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			

FLATULENCE subjects affected / exposed occurrences (all)	2 / 162 (1.23%) 2		
Hepatobiliary disorders HEPATIC STEATOSIS subjects affected / exposed occurrences (all) HEPATOMEGALY subjects affected / exposed occurrences (all)	 3 / 162 (1.85%) 3 0 / 162 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders COUGH subjects affected / exposed occurrences (all)	 5 / 162 (3.09%) 5		
Musculoskeletal and connective tissue disorders ARTHRALGIA subjects affected / exposed occurrences (all)	 3 / 162 (1.85%) 3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 November 2013	This study was initially designed to follow-up patients from various Novartis feeder studies for 2 years which was later shortened to 48 weeks.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
15 May 2015	After a comprehensive portfolio review, and in ight of the advancement of several successful oral anti-HCV agents, Novartis decided to no longer focus on HCV development. The compound DEB025 has been returned to the company from which it was licensed. This decision was not in any way affected or influenced by new safety data for DEB025.	-

Notes:

Limitations and caveats

None reported