

**Clinical trial results:**

A phase III, randomised, double-blind and placebo controlled study of once daily BI 201335, 240 mg for 12 or 24 weeks in combination with pegylated interferon- a (PegIFNa) and ribavirin (RBV) in patients with genotype 1 chronic hepatitis C infection who failed a prior PegIFN/RBV treatment

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2010-021715-17
Trial protocol	GB PT BE DE AT ES
Global end of trial date	15 May 2014

Results information

Result version number	v2 (current)
This version publication date	23 July 2016
First version publication date	26 July 2015
Version creation reason	<ul style="list-style-type: none">• Correction of full data set Data correction due to a system error in EudraCT- Results

Trial information**Trial identification**

Sponsor protocol code	1220.7
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01358864
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173 , Ingelheim am Rhein, Germany, 55216
Public contact	QRPE Processes and Systems Coordination Clinical Trial Information Disclosure, Boehringer Ingelheim , +1 800 243 0127, clintrriage.rdg@boehringer-ingelheim.com
Scientific contact	QRPE Processes and Systems Coordination Clinical Trial Information Disclosure, Boehringer Ingelheim , +1 800 243 0127, clintrriage.rdg@boehringer-ingelheim.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	No

1901/2006 apply to this trial?

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 June 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	15 May 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this trial is to evaluate the efficacy and the safety of BI 201335 given for 12 or 24 weeks in combination with PegIFN/RBV given for 48 weeks as compared to PegIFN/RBV alone in chronic GT-1 hepatitis C virus infected patients who failed a prior PegIFN/RBV treatment.

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were to be entered in the study. All subjects were free to withdraw from the clinical trial at any time for any reason given. Close monitoring of all subjects was adhered to throughout the trial conduct. In addition IDMC meetings were held approximately every four months at the project level; trial data were reviewed in open and closed sessions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 July 2011
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	Belgium: 39
Country: Number of subjects enrolled	Canada: 74
Country: Number of subjects enrolled	France: 116
Country: Number of subjects enrolled	Germany: 70
Country: Number of subjects enrolled	Austria: 29
Country: Number of subjects enrolled	Japan: 153
Country: Number of subjects enrolled	Portugal: 46
Country: Number of subjects enrolled	Spain: 126
Country: Number of subjects enrolled	Switzerland: 43
Country: Number of subjects enrolled	United Kingdom: 65
Country: Number of subjects enrolled	United States: 103
Worldwide total number of subjects	864
EEA total number of subjects	491

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)	788
From 65 to 84 years	76
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All subjects were screened for eligibility to participate in the trial. Subjects attended specialist sites which would then ensure that they (the subjects) met all strictly implemented inclusion/exclusion criteria. Subjects were not to be randomised to trial treatment if any one of the specific entry criteria were violated.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Relapser:Placebo

Arm description:

Patients who had had a prior relapse, received 2 soft gelatin capsules identical to those containing Faldaprevir once daily (orally) and PegIFN/RBV (Pegylated interferon alpha-2a/Ribavirin) administered by injection, for 24 weeks, followed by PegIFN/RBV for 24 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

2 soft gelatin capsules identical to those containing Faldaprevir administered orally for 24 weeks.

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

Dosage and administration details:

1000 (<75 kilograms [kg] body weight) –1200mg (≥75 kg body weight) in 2 divided doses;
600 mg (≤60 kg body weight), 800 mg (>60 AND ≤80 kg body weight), 1000 mg (>80 kg body weight)
(only for Japan) in 2 divided doses

Investigational medicinal product name	Pegylated interferon alpha-2a
Investigational medicinal product code	Pegasys ®
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

180 micrograms (µcg)/0.5 mL pre-filled syringes (except Japan) once weekly
180 µcg/1 mL clear glass vials (only for Japan) once weekly

Arm title	Relapser: Faldaprevir 12 weeks
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Arm description:

Patients who had had a prior relapse, received Faldaprevir (BI 201335) 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 12 weeks, followed by placebo once daily combined with PegIFN/RBV for 12 weeks. At week 24, if the patients did not achieve early treatment success (ETS) the patients received an additional 24 weeks of PegIFN/RBV alone.

Arm type	Experimental
Investigational medicinal product name	Faldaprevir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

A loading dose of 480 mg of Faldaprevir (FDV) was administered orally on the first day of administration, followed by 240 mg once daily from the second day on.

Investigational medicinal product name	Pegylated interferon alpha-2a
Investigational medicinal product code	Pegasys ®
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

180 micrograms (µg)/0.5 mL pre-filled syringes (except Japan) once weekly
180 µg/1 mL clear glass vials (only for Japan) once weekly

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

Dosage and administration details:

1000 (<75 kilograms [kg] body weight) –1200mg (≥75 kg body weight) in 2 divided doses;
600 mg (≤60 kg body weight), 800 mg (>60 AND ≤80 kg body weight), 1000 mg (>80 kg body weight) (only for Japan) in 2 divided doses

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

2 soft gelatin capsules identical to those containing Faldaprevir administered orally for last 12 weeks.

Arm title	Relapser:Faldaprevir 24 weeks
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Arm description:

Patients who had had a prior relapse, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 24 weeks. At week 24, if the patients did not achieve early treatment success (ETS) the patients received an additional 24 weeks of PegIFN/RBV alone.

Arm type	Experimental
Investigational medicinal product name	Faldaprevir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

A loading dose of 480 mg of Faldaprevir (FDV) was administered orally on the first day of administration, followed by 240 mg once daily from the second day on.

Investigational medicinal product name	Pegylated interferon alpha-2a
Investigational medicinal product code	Pegasys ®
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

180 micrograms (µcg)/0.5 mL pre-filled syringes (except Japan) once weekly

180 µcg/1 mL clear glass vials (only for Japan) once weekly

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

Dosage and administration details:

1000 (<75 kilograms [kg] body weight) –1200mg (≥75 kg body weight) in 2 divided doses;

600 mg (≤60 kg body weight), 800 mg (>60 AND ≤80 kg body weight), 1000 mg (>80 kg body weight) (only for Japan) in 2 divided doses

Arm title	Partial:Placebo
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Arm description:

Patients who had had a prior partial response, received 2 soft gelatin capsules identical to those containing Faldaprevir once daily (orally) and PegIFN/RBV (Pegylated interferon alpha-2a/Ribavirin) administered by injection, for 24 weeks, followed by PegIFN/RBV for 24 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

2 soft gelatin capsules identical to those containing Faldaprevir administered orally for 24 weeks.

Investigational medicinal product name	Pegylated interferon alpha-2a
Investigational medicinal product code	Pegasys ®
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

180 micrograms (µcg)/0.5 mL pre-filled syringes (except Japan) once weekly

180 µcg/1 mL clear glass vials (only for Japan) once weekly

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

Dosage and administration details:

1000 (<75 kilograms [kg] body weight) –1200mg (≥75 kg body weight) in 2 divided doses;

600 mg (≤60 kg body weight), 800 mg (>60 AND ≤80 kg body weight), 1000 mg (>80 kg body weight) (only for Japan) in 2 divided doses

Arm title	Partial:Faldaprevir 12 weeks
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Arm description:

Patients who had had a prior partial response, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 12 weeks, followed by placebo once daily combined with PegIFN/RBV for 12 weeks. Followed by PegIFN/RBV alone for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	Faldaprevir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

A loading dose of 480 mg of Faldaprevir (FDV) was administered orally on the first day of administration, followed by 240 mg once daily from the second day on.

Investigational medicinal product name	Pegylated interferon alpha-2a
Investigational medicinal product code	Pegasys ®
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

180 micrograms (µcg)/0.5 mL pre-filled syringes (except Japan) once weekly
180 µcg/1 mL clear glass vials (only for Japan) once weekly

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

Dosage and administration details:

1000 (<75 kilograms [kg] body weight) –1200mg (≥75 kg body weight) in 2 divided doses;
600 mg (≤60 kg body weight), 800 mg (>60 AND ≤80 kg body weight), 1000 mg (>80 kg body weight) (only for Japan) in 2 divided doses

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

2 soft gelatin capsules identical to those containing Faldaprevir administered orally for last 12 weeks.

Arm title	Partial:Faldaprevir 24 weeks
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Arm description:

Patients who had had a prior partial response, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 24 weeks. Followed by PegIFN/RBV alone for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	Faldaprevir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

A loading dose of 480 mg of Faldaprevir (FDV) was administered orally on the first day of

administration, followed by 240 mg once daily from the second day on.

Investigational medicinal product name	Pegylated interferon alpha-2a
Investigational medicinal product code	Pegasys ®
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

180 micrograms (µcg)/0.5 mL pre-filled syringes (except Japan) once weekly

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

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1000 (<75 kilograms [kg] body weight) –1200mg (≥75 kg body weight) in 2 divided doses;

600 mg (≤60 kg body weight), 800 mg (>60 AND ≤80 kg body weight), 1000 mg (>80 kg body weight) (only for Japan) in 2 divided doses

Arm title	Null:Faldaprevir 12 weeks
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Arm description:

Patients who had had a prior null response received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 12 weeks, followed by placebo once daily combined with PegIFN/RBV for 12 weeks. Followed by PegIFN/RBV alone for 24 weeks.

One patient was randomised to the Null:Faldaprevir 12 weeks arm, however this patient was not treated. Consequently, even though the actual number of subjects that started is 146, only 145 were reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Arm type	Experimental
Investigational medicinal product name	Faldaprevir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

A loading dose of 480 mg of Faldaprevir (FDV) was administered orally on the first day of administration, followed by 240 mg once daily from the second day on.

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

Dosage and administration details:

1000 (<75 kilograms [kg] body weight) –1200mg (≥75 kg body weight) in 2 divided doses;

600 mg (≤60 kg body weight), 800 mg (>60 AND ≤80 kg body weight), 1000 mg (>80 kg body weight) (only for Japan) in 2 divided doses

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

2 soft gelatin capsules identical to those containing Faldaprevir administered orally for last 12 weeks.

Investigational medicinal product name	Pegylated interferon alpha-2a
Investigational medicinal product code	Pegasys ®
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

180 micrograms (µcg)/0.5 mL pre-filled syringes (except Japan) once weekly

180 µcg/1 mL clear glass vials (only for Japan) once weekly

Arm title	Null:Faldaprevir 24 weeks
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Arm description:

Patients who had had a prior null response received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 24 weeks. Followed by PegIFN/RBV alone for 24 weeks.

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Investigational medicinal product name	Faldaprevir
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Dosage and administration details:

A loading dose of 480 mg of Faldaprevir (FDV) was administered orally on the first day of administration, followed by 240 mg once daily from the second day on.

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Other name	
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Dosage and administration details:

1000 (<75 kilograms [kg] body weight) –1200mg (≥75 kg body weight) in 2 divided doses;
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(only for Japan) in 2 divided doses

Investigational medicinal product name	Pegylated interferon alpha-2a
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Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

180 micrograms (µcg)/0.5 mL pre-filled syringes (except Japan) once weekly

180 µcg/1 mL clear glass vials (only for Japan) once weekly

Number of subjects in period 1 ^[1]	Relapser:Placebo	Relapser: Faldaprevir 12 weeks	Relapser:Faldaprevir 24 weeks
Started	49	99	103
Completed	18	86	87
Not completed	31	13	16
Other reason not defined above	2	-	-
Consent withdrawn by subject	3	4	2
Adverse event, non-fatal	-	6	9
Lost to follow-up	-	-	1
Lack of efficacy	26	3	4

Number of subjects in period 1 ^[1]	Partial:Placebo	Partial:Faldaprevir 12 weeks	Partial:Faldaprevir 24 weeks
Started	29	57	55
Completed	10	46	42
Not completed	19	11	13
Other reason not defined above	-	-	-
Consent withdrawn by subject	-	-	1
Adverse event, non-fatal	-	4	8
Lost to follow-up	-	-	-
Lack of efficacy	19	7	4

Number of subjects in period 1 ^[1]	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks
Started	145	140
Completed	81	85
Not completed	64	55
Other reason not defined above	2	-
Consent withdrawn by subject	1	3
Adverse event, non-fatal	12	7
Lost to follow-up	-	1
Lack of efficacy	49	44

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Baseline characteristics are based on patients who were randomised after successfully completing the screening period and received at least one of the study medication.

Baseline characteristics

Reporting groups

Reporting group title	Relapser:Placebo
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Reporting group description:

Patients who had had a prior relapse, received 2 soft gelatin capsules identical to those containing Faldaprevir once daily (orally) and PegIFN/RBV (Pegylated interferon alpha-2a/Ribavirin) administered by injection, for 24 weeks, followed by PegIFN/RBV for 24 weeks.

Reporting group title	Relapser: Faldaprevir 12 weeks
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Reporting group description:

Patients who had had a prior relapse, received Faldaprevir (BI 201335) 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 12 weeks, followed by placebo once daily combined with PegIFN/RBV for 12 weeks. At week 24, if the patients did not achieve early treatment success (ETS) the patients received an additional 24 weeks of PegIFN/RBV alone.

Reporting group title	Relapser:Faldaprevir 24 weeks
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Reporting group description:

Patients who had had a prior relapse, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 24 weeks. At week 24, if the patients did not achieve early treatment success (ETS) the patients received an additional 24 weeks of PegIFN/RBV alone.

Reporting group title	Partial:Placebo
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Reporting group description:

Patients who had had a prior partial response, received 2 soft gelatin capsules identical to those containing Faldaprevir once daily (orally) and PegIFN/RBV (Pegylated interferon alpha-2a/Ribavirin) administered by injection, for 24 weeks, followed by PegIFN/RBV for 24 weeks.

Reporting group title	Partial:Faldaprevir 12 weeks
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Reporting group description:

Patients who had had a prior partial response, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 12 weeks, followed by placebo once daily combined with PegIFN/RBV for 12 weeks. Followed by PegIFN/RBV alone for 24 weeks.

Reporting group title	Partial:Faldaprevir 24 weeks
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Reporting group description:

Patients who had had a prior partial response, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 24 weeks. Followed by PegIFN/RBV alone for 24 weeks.

Reporting group title	Null:Faldaprevir 12 weeks
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Reporting group description:

Patients who had had a prior null response received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 12 weeks, followed by placebo once daily combined with PegIFN/RBV for 12 weeks. Followed by PegIFN/RBV alone for 24 weeks.

One patient was randomised to the Null:Faldaprevir 12 weeks arm, however this patient was not treated. Consequently, even though the actual number of subjects that started is 146, only 145 were reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Reporting group title	Null:Faldaprevir 24 weeks
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Reporting group description:

Patients who had had a prior null response received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 24 weeks. Followed by PegIFN/RBV alone for 24 weeks.

Reporting group values	Relapser:Placebo	Relapser: Faldaprevir 12 weeks	Relapser:Faldaprevir 24 weeks
Number of subjects	49	99	103
Age categorical Units: Subjects			

Age Continuous			
Full analysis set (FAS)- included all randomised patients who were dispensed study medication and were documented to have taken at least one dose of study medication.			
Units: years			
arithmetic mean	53.4	53.5	53.7
standard deviation	± 8.29	± 8.57	± 8.14
Gender, Male/Female			
Units: participants			
Female	20	44	43
Male	29	55	60

Reporting group values	Partial:Placebo	Partial:Faldaprevir 12 weeks	Partial:Faldaprevir 24 weeks
Number of subjects	29	57	55
Age categorical Units: Subjects			

Age Continuous			
Full analysis set (FAS)- included all randomised patients who were dispensed study medication and were documented to have taken at least one dose of study medication.			
Units: years			
arithmetic mean	55.7	52.7	52
standard deviation	± 7.5	± 7.9	± 10.32
Gender, Male/Female			
Units: participants			
Female	10	20	20
Male	19	37	35

Reporting group values	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks	Total
Number of subjects	145	140	677
Age categorical Units: Subjects			

Age Continuous			
Full analysis set (FAS)- included all randomised patients who were dispensed study medication and were documented to have taken at least one dose of study medication.			
Units: years			
arithmetic mean	53.2	53.6	
standard deviation	± 8.76	± 8.13	-
Gender, Male/Female			
Units: participants			
Female	54	63	274
Male	91	77	403

End points

End points reporting groups

Reporting group title	Relapser:Placebo
Reporting group description: Patients who had had a prior relapse, received 2 soft gelatin capsules identical to those containing Faldaprevir once daily (orally) and PegIFN/RBV (Pegylated interferon alpha-2a/Ribavirin) administered by injection, for 24 weeks, followed by PegIFN/RBV for 24 weeks.	
Reporting group title	Relapser: Faldaprevir 12 weeks
Reporting group description: Patients who had had a prior relapse, received Faldaprevir (BI 201335) 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 12 weeks, followed by placebo once daily combined with PegIFN/RBV for 12 weeks. At week 24, if the patients did not achieve early treatment success (ETS) the patients received an additional 24 weeks of PegIFN/RBV alone.	
Reporting group title	Relapser:Faldaprevir 24 weeks
Reporting group description: Patients who had had a prior relapse, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 24 weeks. At week 24, if the patients did not achieve early treatment success (ETS) the patients received an additional 24 weeks of PegIFN/RBV alone.	
Reporting group title	Partial:Placebo
Reporting group description: Patients who had had a prior partial response, received 2 soft gelatin capsules identical to those containing Faldaprevir once daily (orally) and PegIFN/RBV (Pegylated interferon alpha-2a/Ribavirin) administered by injection, for 24 weeks, followed by PegIFN/RBV for 24 weeks.	
Reporting group title	Partial:Faldaprevir 12 weeks
Reporting group description: Patients who had had a prior partial response, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 12 weeks, followed by placebo once daily combined with PegIFN/RBV for 12 weeks. Followed by PegIFN/RBV alone for 24 weeks.	
Reporting group title	Partial:Faldaprevir 24 weeks
Reporting group description: Patients who had had a prior partial response, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 24 weeks. Followed by PegIFN/RBV alone for 24 weeks.	
Reporting group title	Null:Faldaprevir 12 weeks
Reporting group description: Patients who had had a prior null response received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 12 weeks, followed by placebo once daily combined with PegIFN/RBV for 12 weeks. Followed by PegIFN/RBV alone for 24 weeks.	
One patient was randomised to the Null:Faldaprevir 12 weeks arm, however this patient was not treated. Consequently, even though the actual number of subjects that started is 146, only 145 were reported to ensure consistent reporting with baseline characteristics that includes only treated patients.	
Reporting group title	Null:Faldaprevir 24 weeks
Reporting group description: Patients who had had a prior null response received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 24 weeks. Followed by PegIFN/RBV alone for 24 weeks.	
Subject analysis set title	Relapser & partial: Placebo
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Patients who had had a prior relapse or prior partial relapse, received 2 soft gelatin capsules identical to those containing Faldaprevir once daily (orally) and PegIFN/RBV administered by injection, for 24 weeks, followed by PegIFN/RBV for 24 weeks.

Subject analysis set title	Relapser & partial: Faldaprevir 12 weeks
Subject analysis set type	Full analysis

Subject analysis set description:

Patients who had had a prior partial relapse, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 12 weeks, followed by placebo once daily combined with PegIFN/RBV for 12 weeks. Followed by PegIFN/RBV alone for 24 weeks (for the partial relapsers the last 24 weeks was only if the patient did not achieve early treatment success (ETS)).

Subject analysis set title	Relapser & partial: Faldaprevir 24 weeks
Subject analysis set type	Full analysis

Subject analysis set description:

Patients who had had a prior partial relapse, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 24 weeks. Followed by PegIFN/RBV alone for 24 weeks (for the partial relapsers the last 24 weeks was only if the patient did not achieve early treatment success (ETS)).

Primary: Sustained Virological Response 12 weeks post treatment (SVR12)

End point title	Sustained Virological Response 12 weeks post treatment (SVR12) ^[1]
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End point description:

Percentage of participants with sustained virological response (SVR12) 12 weeks post treatment defined as plasma Hepatitis C virus Ribonucleic acid (HCV RNA) level <25 IU/mL (undetected) 12 weeks after the originally planned treatment duration.

End point type	Primary
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End point timeframe:

12 weeks post treatment, up to 60 weeks

Notes:

[1] - 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 those arms for which the statistics are presented in the clinical trial report thus, those that would yield meaningful results were reported.

End point values	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks	Relapser & partial: Placebo	Relapser & partial: Faldaprevir 12 weeks
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	145 ^[2]	140 ^[3]	78 ^[4]	156 ^[5]
Units: percentage of participants				
number (confidence interval 95%)	33.8 (26.1 to 41.5)	32.9 (25.1 to 40.6)	10.3 (3.5 to 17)	65.4 (57.9 to 72.9)

Notes:

[2] - FAS

[3] - FAS

[4] - FAS

[5] - FAS

End point values	Relapser & partial: Faldaprevir 24 weeks			
Subject group type	Subject analysis set			
Number of subjects analysed	158 ^[6]			

Units: percentage of participants				
number (confidence interval 95%)	61.4 (53.8 to 69)			

Notes:

[6] - FAS

Statistical analyses

Statistical analysis title	Statistical Analysis 1
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Statistical analysis description:

A stratified Cochran-MantelHaenszel test was used, where strata were defined by GT-1a, 1b, other subtype, and previous response to treatment (relapse yes/no).

Comparison of active-treatment vs placebo.

Comparison groups	Relapser & partial: Placebo v Relapser & partial: Faldaprevir 12 weeks
Number of subjects included in analysis	234
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 ^[7]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percent difference
Point estimate	54.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	44.4
upper limit	65

Notes:

[7] - Adjusted for genotype and previous response to treatment

Statistical analysis title	Statistical Analysis 2
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Statistical analysis description:

A stratified Cochran-MantelHaenszel test was used, where strata were defined by GT-1a, 1b, other subtype, and previous response to treatment (relapse yes/no).

Comparison of active-treatment vs placebo.

Comparison groups	Relapser & partial: Placebo v Relapser & partial: Faldaprevir 24 weeks
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 ^[8]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percent difference
Point estimate	50.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.1
upper limit	60.8

Notes:

[8] - Adjusted for genotype and previous response to treatment

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
A stratified Cochran-MantelHaenszel test was used, where strata were defined by GT-1a, 1b, other subtype, and previous response to treatment (relapse yes/no).	
Comparison of FDV 24 weeks vs FDV 12 weeks	
Comparison groups	Relapser & partial: Faldaprevir 12 weeks v Relapser & partial: Faldaprevir 24 weeks
Number of subjects included in analysis	314
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Adjusted percent difference
Point estimate	4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.8
upper limit	14.9

Statistical analysis title	Statistical Analysis 4
Statistical analysis description:	
A stratified Cochran-MantelHaenszel test was used, where strata were defined by GT-1a, 1b, other subtype, and previous response to treatment (relapse yes/no).	
Comparison of FDV 24 weeks vs FDV 12 weeks .	
Comparison groups	Null:Faldaprevir 12 weeks v Null:Faldaprevir 24 weeks
Number of subjects included in analysis	285
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Adjusted percent difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.9
upper limit	10.7

Secondary: Virological response after 24 weeks of treatment discontinuation (SVR24)

End point title	Virological response after 24 weeks of treatment discontinuation (SVR24) ^[9]
End point description:	
Percentage of participants with virological response after 24 weeks of treatment discontinuation (SVR24) defined as plasma Hepatitis C virus Ribonucleic acid (HCV RNA) level <25 IU/mL (undetected) 24 weeks after the originally planned treatment duration.	
End point type	Secondary
End point timeframe:	
24 weeks post treatment, up to 72 weeks	

Notes:

[9] - 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 those arms for which the statistics are presented in the clinical trial report thus, those that would yield meaningful results were reported.

End point values	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks	Relapser & partial: Placebo	Relapser & partial: Faldaprevir 12 weeks
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	145 ^[10]	140 ^[11]	78 ^[12]	156 ^[13]
Units: percentage of participants				
number (confidence interval 95%)	33.8 (26.1 to 41.5)	32.9 (25.1 to 40.6)	10.3 (3.5 to 17)	63.5 (55.9 to 71)

Notes:

[10] - FAS

[11] - FAS

[12] - FAS

[13] - FAS

End point values	Relapser & partial: Faldaprevir 24 weeks			
Subject group type	Subject analysis set			
Number of subjects analysed	158 ^[14]			
Units: percentage of participants				
number (confidence interval 95%)	59.5 (51.8 to 67.1)			

Notes:

[14] - FAS

Statistical analyses

Statistical analysis title	Statistical Analysis 1
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Statistical analysis description:

A stratified Cochran-MantelHaenszel test was used, where strata were defined by GT-1a, 1b, other subtype, and previous response to treatment (relapse yes/no).

Comparison of active-treatment vs placebo.

Comparison groups	Relapser & partial: Placebo v Relapser & partial: Faldaprevir 12 weeks
Number of subjects included in analysis	234
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 ^[15]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percent difference
Point estimate	52.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	42.4
upper limit	63.2

Notes:

[15] - Adjusted for genotype and previous response to treatment

Statistical analysis title	Statistical Analysis 2
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Statistical analysis description:

A stratified Cochran-MantelHaenszel test was used, where strata were defined by GT-1a, 1b, other subtype, and previous response to treatment (relapse yes/no).

Comparison of active-treatment vs placebo.

Comparison groups	Relapser & partial: Placebo v Relapser & partial: Faldaprevir 24 weeks
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 ^[16]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percent difference
Point estimate	48.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	38.2
upper limit	58.9

Notes:

[16] - Adjusted for genotype and previous response to treatment

Statistical analysis title	Statistical Analysis 3
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Statistical analysis description:

A stratified Cochran-MantelHaenszel test was used, where strata were defined by GT-1a, 1b, other subtype, and previous response to treatment (relapse yes/no).

Comparison of FDV 24 weeks vs FDV 12 weeks

Comparison groups	Relapser & partial: Faldaprevir 12 weeks v Relapser & partial: Faldaprevir 24 weeks
Number of subjects included in analysis	314
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Adjusted percent difference
Point estimate	4.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	14.9

Statistical analysis title	Statistical Analysis 4
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Statistical analysis description:

A stratified Cochran-MantelHaenszel test was used, where strata were defined by GT-1a, 1b, other subtype, and previous response to treatment (relapse yes/no).

Comparison of FDV 24 weeks vs FDV 12 weeks.

Comparison groups	Null:Faldaprevir 12 weeks v Null:Faldaprevir 24 weeks
Number of subjects included in analysis	285
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Adjusted percent difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.9
upper limit	10.7

Secondary: Early Treatment Success (ETS)

End point title	Early Treatment Success (ETS)
End point description:	Percentage of participants with early Treatment Success (ETS) defined as a plasma HCV RNA level <25 IU/mL (undetected or detected) at Week 4 and <25 IU/mL (undetected) at Week 8.
End point type	Secondary
End point timeframe:	
Week 4 and Week 8	

End point values	Relapser:Placebo	Relapser:Faldaprevir 12 weeks	Relapser:Faldaprevir 24 weeks	Partial:Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49 ^[17]	99 ^[18]	103 ^[19]	29 ^[20]
Units: percentage of participants				
number (not applicable)	4.1	85.9	87.4	3.4

Notes:

[17] - FAS

[18] - FAS

[19] - FAS

[20] - FAS

End point values	Partial:Faldaprevir 12 weeks	Partial:Faldaprevir 24 weeks	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[21]	55 ^[22]	145 ^[23]	140 ^[24]
Units: percentage of participants				
number (not applicable)	66.7	76.4	58.6	51.4

Notes:

[21] - FAS

[22] - FAS

[23] - FAS

[24] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: ALT Normalisation: ALT in Normal Range at End of Treatment, When SVR12=NO

End point title	ALT Normalisation: ALT in Normal Range at End of Treatment, When SVR12=NO
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End point description:

The number of participants with alanine aminotransferase (ALT) in normal range at the end of treatment (EoT) when patients do not have sustained virological response 12 weeks post treatment. BL=baseline

End point type	Secondary
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End point timeframe:

End of treatment, up to 48 weeks

End point values	Relapser:Placebo	Relapser:Faldaprevir 12 weeks	Relapser:Faldaprevir 24 weeks	Partial:Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49 ^[25]	99 ^[26]	103 ^[27]	29 ^[28]
Units: participants				
number (not applicable)				
SVR12=NO	42	30	31	28
BL normal to EoT normal	9	9	6	3
BL elevated to EoT normal	15	10	14	9
No EoT data available for ALT	1	0	0	0

Notes:

[25] - FAS

[26] - FAS

[27] - FAS

[28] - FAS

End point values	Partial:Faldaprevir 12 weeks	Partial:Faldaprevir 24 weeks	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[29]	55 ^[30]	145 ^[31]	140 ^[32]
Units: participants				
number (not applicable)				
SVR12=NO	24	30	96	94
BL normal to EoT normal	4	4	15	14
BL elevated to EoT normal	14	6	34	38
No EoT data available for ALT	0	1	1	0

Notes:

[29] - FAS

[30] - FAS

[31] - FAS

[32] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: ALT Normalisation: ALT in Normal Range at End of Treatment, When SVR12=YES

End point title	ALT Normalisation: ALT in Normal Range at End of Treatment, When SVR12=YES
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End point description:

The number of participants with alanine aminotransferase (ALT) in normal range at the end of treatment when patients have sustained virological response 12 weeks post treatment. BL=baseline

End point type	Secondary
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End point timeframe:

End of treatment, up to 48 weeks

End point values	Relapser:Placebo	Relapser:Faldaprevir 12 weeks	Relapser:Faldaprevir 24 weeks	Partial:Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49 ^[33]	99 ^[34]	103 ^[35]	29 ^[36]
Units: participants				
number (not applicable)				
SVR12=YES	7	69	72	1
BL normal to EoT normal	3	30	30	0
BL elevated to EoT normal	4	29	26	1

Notes:

[33] - FAS

[34] - FAS

[35] - FAS

[36] - FAS

End point values	Partial:Faldaprevir 12 weeks	Partial:Faldaprevir 24 weeks	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[37]	55 ^[38]	145 ^[39]	140 ^[40]
Units: participants				
number (not applicable)				
SVR12=YES	33	25	49	46
BL normal to EoT normal	10	8	12	9
BL elevated to EoT normal	14	8	23	27

Notes:

[37] - FAS

[38] - FAS

[39] - FAS

[40] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: AST Normalisation: AST in Normal Range at End of Treatment, When SVR12=NO

End point title	AST Normalisation: AST in Normal Range at End of Treatment, When SVR12=NO
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End point description:

The number of participants with aspartate aminotransferase (AST) in normal range at the end of treatment when patients do not have sustained virological response 12 weeks post treatment.

BL=baseline

End point type	Secondary
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End point timeframe:

End of treatment, up to 48 weeks

End point values	Relapser:Placebo	Relapser:Faldaprevir 12 weeks	Relapser:Faldaprevir 24 weeks	Partial:Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49 ^[41]	99 ^[42]	103 ^[43]	29 ^[44]
Units: participants				
number (not applicable)				
SVR12=NO	42	30	31	28
BL normal to EoT normal	19	16	12	4
BL elevated to EoT normal	5	5	9	9

Notes:

[41] - FAS

[42] - FAS

[43] - FAS

[44] - FAS

End point values	Partial:Faldaprevir 12 weeks	Partial:Faldaprevir 24 weeks	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[45]	55 ^[46]	145 ^[47]	140 ^[48]
Units: participants				
number (not applicable)				
SVR12=NO	24	30	96	94
BL normal to EoT normal	3	5	18	21
BL elevated to EoT normal	14	6	24	28

Notes:

[45] - FAS

[46] - FAS

[47] - FAS

[48] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: AST Normalisation: AST in Normal Range at End of Treatment, When SVR12=YES

End point title	AST Normalisation: AST in Normal Range at End of Treatment, When SVR12=YES
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End point description:

The number of participants with aspartate aminotransferase (AST) in normal range at the end of treatment (EoT) when patients have sustained virological response 12 weeks post treatment.

BL=baseline

End point type	Secondary
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End point timeframe:

End of treatment, up to 48 weeks

End point values	Relapser:Placebo	Relapser:Faldaprevir 12 weeks	Relapser:Faldaprevir 24 weeks	Partial:Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49 ^[49]	99 ^[50]	103 ^[51]	29 ^[52]
Units: participants				
number (not applicable)				
SVR12=YES	7	69	72	1
BL normal to EoT normal	2	35	39	0
BL elevated to EoT normal	4	24	22	1
No EoT data available for AST	1	0	0	0

Notes:

[49] - FAS

[50] - FAS

[51] - FAS

[52] - FAS

End point values	Partial:Faldaprevir 12 weeks	Partial:Faldaprevir 24 weeks	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[53]	55 ^[54]	145 ^[55]	140 ^[56]
Units: participants				
number (not applicable)				
SVR12=YES	33	25	49	46
BL normal to EoT normal	13	10	15	16
BL elevated to EoT normal	10	9	21	20
No EoT data available for AST	0	1	1	0

Notes:

[53] - FAS

[54] - FAS

[55] - FAS

[56] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: ALT Normalisation: ALT in Normal Range 12 weeks Post Treatment, When SVR12=NO

End point title	ALT Normalisation: ALT in Normal Range 12 weeks Post Treatment, When SVR12=NO
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End point description:

The number of participants with alanine aminotransferase (ALT) in normal range post treatment when patients do not have sustained virological response 12 weeks post treatment. BL=baseline

End point type	Secondary
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End point timeframe:

12 weeks post treatment, up to 60 weeks

End point values	Relapser:Placebo	Relapser:Faldaprevir 12 weeks	Relapser:Faldaprevir 24 weeks	Partial:Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49 ^[57]	99 ^[58]	103 ^[59]	29 ^[60]
Units: participants				
number (not applicable)				
SVR12=NO	42	30	31	28
BL normal to SVR12 normal	0	9	6	0
BL elevated to SVR12 normal	1	6	6	0
No ALT data available at SVR12 visit	33	7	3	3

Notes:

[57] - FAS

[58] - FAS

[59] - FAS

[60] - FAS

End point values	Partial:Faldaprevir 12 weeks	Partial:Faldaprevir 24 weeks	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[61]	55 ^[62]	145 ^[63]	140 ^[64]
Units: participants				
number (not applicable)				
SVR12=NO	24	30	96	94
BL normal to SVR12 normal	2	4	11	6
BL elevated to SVR12 normal	4	3	7	9
No ALT data available at SVR12 visit	6	5	27	30

Notes:

[61] - FAS

[62] - FAS

[63] - FAS

[64] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: ALT Normalisation: ALT in Normal Range 12 weeks Post Treatment, SVR12=YES

End point title	ALT Normalisation: ALT in Normal Range 12 weeks Post Treatment, SVR12=YES
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End point description:

The number of participants with alanine aminotransferase (ALT) in normal range post treatment when patients have sustained virological response 12 weeks post treatment. BL=baseline

End point type	Secondary
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End point timeframe:

12 weeks post treatment, up to 60 weeks

End point values	Relapser:Placebo	Relapser:Faldaprevir 12 weeks	Relapser:Faldaprevir 24 weeks	Partial:Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49 ^[65]	99 ^[66]	103 ^[67]	29 ^[68]
Units: participants				
number (not applicable)				
SVR12=YES	7	69	72	1
BL normal to SVR12 normal	3	31	31	0
BL elevated to SVR12 normal	3	35	38	1
No ALT data available at SVR12 visit	1	1	0	0

Notes:

[65] - FAS

[66] - FAS

[67] - FAS

[68] - FAS

End point values	Partial:Faldaprevir 12 weeks	Partial:Faldaprevir 24 weeks	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[69]	55 ^[70]	145 ^[71]	140 ^[72]
Units: participants				
number (not applicable)				
SVR12=YES	33	25	49	46
BL normal to SVR12 normal	13	10	13	10
BL elevated to SVR12 normal	20	11	32	35
No ALT data available at SVR12 visit	0	0	1	0

Notes:

[69] - FAS

[70] - FAS

[71] - FAS

[72] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: AST Normalisation: AST in Normal Range 12 weeks Post Treatment, When SVR12=NO

End point title	AST Normalisation: AST in Normal Range 12 weeks Post Treatment, When SVR12=NO
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End point description:

The number of participants with aspartate aminotransferase (AST) in normal range post treatment when patients do not have sustained virological response 12 weeks post treatment. BL=baseline

End point type	Secondary
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End point timeframe:

12 weeks post treatment, up to 60 weeks

End point values	Relapser:Placebo	Relapser:Faldaprevir 12 weeks	Relapser:Faldaprevir 24 weeks	Partial:Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49 ^[73]	99 ^[74]	103 ^[75]	29 ^[76]
Units: participants				
number (not applicable)				
SVR12=NO	42	30	31	28
BL normal to SVR12 normal	0	14	10	0
BL elevated to SVR12 normal	2	2	6	0
No AST data available at SVR12 visit	33	7	3	23

Notes:

[73] - FAS

[74] - FAS

[75] - FAS

[76] - FAS

End point values	Partial:Faldaprevir 12 weeks	Partial:Faldaprevir 24 weeks	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[77]	55 ^[78]	145 ^[79]	140 ^[80]
Units: participants				
number (not applicable)				
SVR12=NO	24	30	96	94
BL normal to SVR12 normal	3	3	13	14
BL elevated to SVR12 normal	6	3	6	3
No AST data available at SVR12 visit	6	6	27	30

Notes:

[77] - FAS

[78] - FAS

[79] - FAS

[80] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: AST Normalisation: AST in Normal Range 12 weeks Post Treatment, SVR12=YES

End point title	AST Normalisation: AST in Normal Range 12 weeks Post Treatment, SVR12=YES
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End point description:

The number of participants with aspartate aminotransferase (AST) in normal range post treatment when patients have sustained virological response 12 weeks post treatment. BL=baseline

End point type	Secondary
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End point timeframe:

12 weeks post treatment, up to 60 weeks

End point values	Relapser:Placebo	Relapser:Faldaprevir 12 weeks	Relapser:Faldaprevir 24 weeks	Partial:Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49 ^[81]	99 ^[82]	103 ^[83]	29 ^[84]
Units: participants				
number (not applicable)				
SVR12=YES	7	69	72	1
BL normal to SVR12 normal	2	36	41	0
BL elevated to SVR12 normal	4	29	28	1
No AST data available at SVR12 visit	1	1	0	0

Notes:

[81] - FAS

[82] - FAS

[83] - FAS

[84] - FAS

End point values	Partial:Faldaprevir 12 weeks	Partial:Faldaprevir 24 weeks	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[85]	55 ^[86]	145 ^[87]	140 ^[88]
Units: participants				
number (not applicable)				
SVR12=YES	33	25	49	46
BL normal to SVR12 normal	16	13	16	17
BL elevated to SVR12 normal	16	8	28	25
No AST data available at SVR12 visit	0	0	1	0

Notes:

[85] - FAS

[86] - FAS

[87] - FAS

[88] - FAS

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During the course of the study (48 weeks)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.0
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Reporting groups

Reporting group title	Null:Faldaprevir 12 weeks
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Reporting group description:

Patients who had had a prior null response received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 12 weeks, followed by placebo once daily combined with PegIFN/RBV for 12 weeks. Followed by PegIFN/RBV alone for 24 weeks.

Reporting group title	Null:Faldaprevir 24 weeks
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Reporting group description:

Patients who had had a prior null response received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 24 weeks. Followed by PegIFN/RBV alone for 24 weeks.

Reporting group title	Relapser & partial:Faldaprevir 24 weeks
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Reporting group description:

Patients who had had a prior relapse or prior partial response, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 24 weeks. Followed by PegIFN/RBV alone for 24 weeks (for the partial relapsers the last 24 weeks was only if the patient did not achieve early treatment success (ETS)).

Reporting group title	Relapser & partial:Faldaprevir 12 weeks
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Reporting group description:

Patients who had had a prior relapse or prior partial response, received Faldaprevir 240mg once daily, in the form of 2 soft gelatin capsules administered orally, combined with PegIFN/RBV, administered by injection, for 12 weeks, followed by placebo once daily combined with PegIFN/RBV for 12 weeks. Followed by PegIFN/RBV alone for 24 weeks (for the partial relapsers the last 24 weeks was only if the patient did not achieve early treatment success (ETS)).

Reporting group title	Relapser & partial:Placebo
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Reporting group description:

Patients who had had a prior relapse or prior partial response, received 2 soft gelatin capsules identical to those containing Faldaprevir once daily (orally) and PegIFN/RBV administered by injection, for 24 weeks, followed by PegIFN/RBV for 24 weeks.

Serious adverse events	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks	Relapser & partial:Faldaprevir 24 weeks
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 145 (11.03%)	11 / 140 (7.86%)	13 / 158 (8.23%)
number of deaths (all causes)	3	0	2
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			

subjects affected / exposed	0 / 145 (0.00%)	1 / 140 (0.71%)	0 / 158 (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			
Hypertensive crisis			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Venous thrombosis			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
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			
Asthenia			
subjects affected / exposed	0 / 145 (0.00%)	1 / 140 (0.71%)	0 / 158 (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
Chest pain			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Fatigue			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	1 / 145 (0.69%)	1 / 140 (0.71%)	0 / 158 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyrexia			
subjects affected / exposed	3 / 145 (2.07%)	1 / 140 (0.71%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	3 / 3	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric decompensation			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
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 lactate dehydrogenase increased			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio abnormal			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	0 / 158 (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
Injury, poisoning and procedural complications			
Fall			

subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Multiple injuries			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Traumatic haemothorax			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Congenital, familial and genetic disorders			
Keratosis follicular			
subjects affected / exposed	0 / 145 (0.00%)	1 / 140 (0.71%)	0 / 158 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 145 (0.00%)	1 / 140 (0.71%)	0 / 158 (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
Bradycardia			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure congestive			
subjects affected / exposed	0 / 145 (0.00%)	1 / 140 (0.71%)	0 / 158 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Nervous system disorders			
Coma			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Headache			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	0 / 158 (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
Presyncope			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 145 (1.38%)	1 / 140 (0.71%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	2 / 2	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Haemolytic anaemia			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	0 / 158 (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
Thrombocytopenia			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	3 / 158 (1.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	2 / 145 (1.38%)	0 / 140 (0.00%)	0 / 158 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	2 / 145 (1.38%)	2 / 140 (1.43%)	0 / 158 (0.00%)
occurrences causally related to treatment / all	2 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	0 / 158 (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
Nausea			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral lichen planus			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	0 / 158 (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
Pancreatitis acute			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	0 / 158 (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
Peritoneal haemorrhage			

subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Salivary gland calculus			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
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 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
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			
Biliary colic			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	0 / 158 (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
Cholelithiasis			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	0 / 158 (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
Hepatorenal failure			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	0 / 158 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			

subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	0 / 158 (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
Rash generalised			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
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 colic			
subjects affected / exposed	0 / 145 (0.00%)	1 / 140 (0.71%)	0 / 158 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 145 (0.69%)	0 / 140 (0.00%)	0 / 158 (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
Fasciitis			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint instability			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
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 discomfort			
subjects affected / exposed	0 / 145 (0.00%)	1 / 140 (0.71%)	0 / 158 (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 Appendicitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 145 (0.00%) 0 / 0 0 / 0	1 / 140 (0.71%) 0 / 1 0 / 0	1 / 158 (0.63%) 0 / 1 0 / 0
Cellulitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 145 (0.00%) 0 / 0 0 / 0	0 / 140 (0.00%) 0 / 0 0 / 0	1 / 158 (0.63%) 0 / 1 0 / 0
Gastroenteritis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 145 (0.00%) 0 / 0 0 / 0	1 / 140 (0.71%) 1 / 1 0 / 0	0 / 158 (0.00%) 0 / 0 0 / 0
Gastroenteritis viral subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 145 (0.00%) 0 / 0 0 / 0	1 / 140 (0.71%) 0 / 1 0 / 0	0 / 158 (0.00%) 0 / 0 0 / 0
Peritonitis bacterial subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 145 (0.69%) 0 / 1 0 / 0	0 / 140 (0.00%) 0 / 0 0 / 0	0 / 158 (0.00%) 0 / 0 0 / 0
Pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 145 (0.00%) 0 / 0 0 / 0	0 / 140 (0.00%) 0 / 0 0 / 0	1 / 158 (0.63%) 0 / 1 0 / 0
Sepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 145 (0.69%) 0 / 1 0 / 1	0 / 140 (0.00%) 0 / 0 0 / 0	1 / 158 (0.63%) 1 / 1 0 / 0
Streptococcal infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 145 (0.00%) 0 / 0 0 / 0	0 / 140 (0.00%) 0 / 0 0 / 0	0 / 158 (0.00%) 0 / 0 0 / 0
Viral infection			

subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 145 (0.00%)	1 / 140 (0.71%)	0 / 158 (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
Dehydration			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	0 / 158 (0.00%)
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	1 / 145 (0.69%)	0 / 140 (0.00%)	0 / 158 (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
Hypokalaemia			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 145 (0.00%)	0 / 140 (0.00%)	1 / 158 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Serious adverse events	Relapser & partial:Faldaprevir 12 weeks	Relapser & partial:Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 156 (8.97%)	1 / 78 (1.28%)	
number of deaths (all causes)	2	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 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (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	3 / 156 (1.92%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 156 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	0 / 156 (0.00%)	1 / 78 (1.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric decompensation			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio abnormal			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			

subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (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			
Keratosis follicular			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (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 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (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			
Coma			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic anaemia			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (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	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral lichen planus			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (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 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal haemorrhage			

subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland calculus			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	2 / 156 (1.28%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (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 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatorenal failure			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (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	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			

subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash generalised			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (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			
Back pain			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fasciitis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint instability			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal discomfort			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (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 Appendicitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 156 (0.00%) 0 / 0 0 / 0	0 / 78 (0.00%) 0 / 0 0 / 0	
Cellulitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 156 (0.00%) 0 / 0 0 / 0	0 / 78 (0.00%) 0 / 0 0 / 0	
Gastroenteritis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 156 (0.00%) 0 / 0 0 / 0	0 / 78 (0.00%) 0 / 0 0 / 0	
Gastroenteritis viral subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 156 (0.00%) 0 / 0 0 / 0	0 / 78 (0.00%) 0 / 0 0 / 0	
Peritonitis bacterial subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 156 (0.00%) 0 / 0 0 / 0	0 / 78 (0.00%) 0 / 0 0 / 0	
Pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 156 (0.64%) 0 / 1 0 / 0	0 / 78 (0.00%) 0 / 0 0 / 0	
Sepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 156 (0.00%) 0 / 0 0 / 0	0 / 78 (0.00%) 0 / 0 0 / 0	
Streptococcal infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 156 (0.64%) 1 / 1 0 / 0	0 / 78 (0.00%) 0 / 0 0 / 0	
Viral infection			

subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (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			
Decreased appetite			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	1 / 156 (0.64%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 78 (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	Null:Faldaprevir 12 weeks	Null:Faldaprevir 24 weeks	Relapser & partial:Faldaprevir 24 weeks
Total subjects affected by non-serious adverse events			
subjects affected / exposed	142 / 145 (97.93%)	139 / 140 (99.29%)	156 / 158 (98.73%)
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	24 / 145 (16.55%)	28 / 140 (20.00%)	28 / 158 (17.72%)
occurrences (all)	24	29	28
Chills			
subjects affected / exposed	1 / 145 (0.69%)	8 / 140 (5.71%)	14 / 158 (8.86%)
occurrences (all)	1	9	14
Fatigue			
subjects affected / exposed	45 / 145 (31.03%)	47 / 140 (33.57%)	59 / 158 (37.34%)
occurrences (all)	47	48	62
Influenza like illness			
subjects affected / exposed	27 / 145 (18.62%)	23 / 140 (16.43%)	29 / 158 (18.35%)
occurrences (all)	30	24	29
Injection site erythema			
subjects affected / exposed	4 / 145 (2.76%)	4 / 140 (2.86%)	3 / 158 (1.90%)
occurrences (all)	4	4	3
Malaise			
subjects affected / exposed	4 / 145 (2.76%)	11 / 140 (7.86%)	10 / 158 (6.33%)
occurrences (all)	4	11	10
Pain			
subjects affected / exposed	4 / 145 (2.76%)	4 / 140 (2.86%)	7 / 158 (4.43%)
occurrences (all)	4	4	7
Pyrexia			
subjects affected / exposed	26 / 145 (17.93%)	38 / 140 (27.14%)	25 / 158 (15.82%)
occurrences (all)	28	43	26
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	4 / 145 (2.76%)	3 / 140 (2.14%)	3 / 158 (1.90%)
occurrences (all)	4	4	3
Cough			
subjects affected / exposed	23 / 145 (15.86%)	24 / 140 (17.14%)	27 / 158 (17.09%)
occurrences (all)	25	26	27
Dyspnoea			
subjects affected / exposed	8 / 145 (5.52%)	7 / 140 (5.00%)	16 / 158 (10.13%)
occurrences (all)	8	7	16
Psychiatric disorders			

Depression subjects affected / exposed occurrences (all)	14 / 145 (9.66%) 14	15 / 140 (10.71%) 15	12 / 158 (7.59%) 12
Anxiety subjects affected / exposed occurrences (all)	5 / 145 (3.45%) 5	11 / 140 (7.86%) 12	12 / 158 (7.59%) 12
Insomnia subjects affected / exposed occurrences (all)	18 / 145 (12.41%) 19	29 / 140 (20.71%) 29	35 / 158 (22.15%) 35
Irritability subjects affected / exposed occurrences (all)	10 / 145 (6.90%) 10	13 / 140 (9.29%) 13	16 / 158 (10.13%) 18
Sleep disorder subjects affected / exposed occurrences (all)	8 / 145 (5.52%) 8	10 / 140 (7.14%) 10	5 / 158 (3.16%) 5
Investigations Haemoglobin decreased subjects affected / exposed occurrences (all)	9 / 145 (6.21%) 10	10 / 140 (7.14%) 10	4 / 158 (2.53%) 4
Weight decreased subjects affected / exposed occurrences (all)	8 / 145 (5.52%) 8	8 / 140 (5.71%) 8	2 / 158 (1.27%) 2
Nervous system disorders Disturbance in attention subjects affected / exposed occurrences (all)	2 / 145 (1.38%) 2	4 / 140 (2.86%) 4	9 / 158 (5.70%) 9
Headache subjects affected / exposed occurrences (all)	52 / 145 (35.86%) 55	45 / 140 (32.14%) 45	46 / 158 (29.11%) 46
Dizziness subjects affected / exposed occurrences (all)	9 / 145 (6.21%) 9	5 / 140 (3.57%) 5	11 / 158 (6.96%) 11
Dysgeusia subjects affected / exposed occurrences (all)	7 / 145 (4.83%) 7	12 / 140 (8.57%) 12	12 / 158 (7.59%) 12
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	22 / 145 (15.17%)	19 / 140 (13.57%)	27 / 158 (17.09%)
occurrences (all)	23	22	31
Neutropenia			
subjects affected / exposed	16 / 145 (11.03%)	13 / 140 (9.29%)	18 / 158 (11.39%)
occurrences (all)	17	17	36
Thrombocytopenia			
subjects affected / exposed	13 / 145 (8.97%)	3 / 140 (2.14%)	6 / 158 (3.80%)
occurrences (all)	15	3	6
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	6 / 145 (4.14%)	9 / 140 (6.43%)	4 / 158 (2.53%)
occurrences (all)	6	10	4
Eye disorders			
Ocular icterus			
subjects affected / exposed	6 / 145 (4.14%)	2 / 140 (1.43%)	6 / 158 (3.80%)
occurrences (all)	6	2	6
Dry eye			
subjects affected / exposed	4 / 145 (2.76%)	5 / 140 (3.57%)	7 / 158 (4.43%)
occurrences (all)	4	5	7
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	7 / 145 (4.83%)	13 / 140 (9.29%)	14 / 158 (8.86%)
occurrences (all)	7	16	15
Constipation			
subjects affected / exposed	7 / 145 (4.83%)	7 / 140 (5.00%)	8 / 158 (5.06%)
occurrences (all)	7	7	8
Abdominal pain upper			
subjects affected / exposed	11 / 145 (7.59%)	15 / 140 (10.71%)	15 / 158 (9.49%)
occurrences (all)	11	17	16
Diarrhoea			
subjects affected / exposed	39 / 145 (26.90%)	47 / 140 (33.57%)	59 / 158 (37.34%)
occurrences (all)	47	58	67
Dyspepsia			
subjects affected / exposed	12 / 145 (8.28%)	9 / 140 (6.43%)	13 / 158 (8.23%)
occurrences (all)	12	10	15
Gastrooesophageal reflux disease			

subjects affected / exposed occurrences (all)	3 / 145 (2.07%) 3	6 / 140 (4.29%) 6	0 / 158 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	77 / 145 (53.10%) 82	75 / 140 (53.57%) 79	88 / 158 (55.70%) 93
Vomiting subjects affected / exposed occurrences (all)	46 / 145 (31.72%) 55	37 / 140 (26.43%) 68	47 / 158 (29.75%) 57
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	10 / 145 (6.90%) 10	9 / 140 (6.43%) 9	11 / 158 (6.96%) 11
Jaundice subjects affected / exposed occurrences (all)	16 / 145 (11.03%) 17	16 / 140 (11.43%) 16	27 / 158 (17.09%) 29
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	8 / 145 (5.52%) 8	13 / 140 (9.29%) 13	16 / 158 (10.13%) 16
Dry skin subjects affected / exposed occurrences (all)	19 / 145 (13.10%) 19	31 / 140 (22.14%) 32	29 / 158 (18.35%) 29
Erythema subjects affected / exposed occurrences (all)	11 / 145 (7.59%) 13	12 / 140 (8.57%) 15	9 / 158 (5.70%) 10
Pruritus subjects affected / exposed occurrences (all)	47 / 145 (32.41%) 52	63 / 140 (45.00%) 68	61 / 158 (38.61%) 68
Rash subjects affected / exposed occurrences (all)	38 / 145 (26.21%) 42	41 / 140 (29.29%) 48	44 / 158 (27.85%) 47
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	5 / 145 (3.45%) 5	7 / 140 (5.00%) 8	12 / 158 (7.59%) 12
Arthralgia			

subjects affected / exposed occurrences (all)	10 / 145 (6.90%) 11	15 / 140 (10.71%) 15	21 / 158 (13.29%) 21
Myalgia subjects affected / exposed occurrences (all)	15 / 145 (10.34%) 15	18 / 140 (12.86%) 18	19 / 158 (12.03%) 19
Muscle spasms subjects affected / exposed occurrences (all)	4 / 145 (2.76%) 4	8 / 140 (5.71%) 8	8 / 158 (5.06%) 8
Infections and infestations Influenza subjects affected / exposed occurrences (all)	4 / 145 (2.76%) 4	1 / 140 (0.71%) 1	6 / 158 (3.80%) 6
Nasopharyngitis subjects affected / exposed occurrences (all)	6 / 145 (4.14%) 7	10 / 140 (7.14%) 13	13 / 158 (8.23%) 16
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	27 / 145 (18.62%) 29	36 / 140 (25.71%) 41	32 / 158 (20.25%) 32

Non-serious adverse events	Relapser & partial:Faldaprevir 12 weeks	Relapser & partial:Placebo	
Total subjects affected by non-serious adverse events subjects affected / exposed	148 / 156 (94.87%)	74 / 78 (94.87%)	
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	28 / 156 (17.95%) 28	21 / 78 (26.92%) 22	
Chills subjects affected / exposed occurrences (all)	9 / 156 (5.77%) 9	5 / 78 (6.41%) 5	
Fatigue subjects affected / exposed occurrences (all)	53 / 156 (33.97%) 54	16 / 78 (20.51%) 16	
Influenza like illness subjects affected / exposed occurrences (all)	28 / 156 (17.95%) 29	15 / 78 (19.23%) 15	

Injection site erythema subjects affected / exposed occurrences (all)	1 / 156 (0.64%) 1	4 / 78 (5.13%) 4	
Malaise subjects affected / exposed occurrences (all)	5 / 156 (3.21%) 5	4 / 78 (5.13%) 4	
Pain subjects affected / exposed occurrences (all)	5 / 156 (3.21%) 5	4 / 78 (5.13%) 4	
Pyrexia subjects affected / exposed occurrences (all)	24 / 156 (15.38%) 26	14 / 78 (17.95%) 16	
Respiratory, thoracic and mediastinal disorders			
Epistaxis subjects affected / exposed occurrences (all)	5 / 156 (3.21%) 5	4 / 78 (5.13%) 5	
Cough subjects affected / exposed occurrences (all)	25 / 156 (16.03%) 25	16 / 78 (20.51%) 17	
Dyspnoea subjects affected / exposed occurrences (all)	16 / 156 (10.26%) 16	7 / 78 (8.97%) 7	
Psychiatric disorders			
Depression subjects affected / exposed occurrences (all)	11 / 156 (7.05%) 11	10 / 78 (12.82%) 10	
Anxiety subjects affected / exposed occurrences (all)	9 / 156 (5.77%) 9	3 / 78 (3.85%) 3	
Insomnia subjects affected / exposed occurrences (all)	36 / 156 (23.08%) 36	13 / 78 (16.67%) 13	
Irritability subjects affected / exposed occurrences (all)	10 / 156 (6.41%) 10	11 / 78 (14.10%) 11	
Sleep disorder			

subjects affected / exposed occurrences (all)	4 / 156 (2.56%) 4	3 / 78 (3.85%) 3	
Investigations			
Haemoglobin decreased			
subjects affected / exposed	6 / 156 (3.85%)	2 / 78 (2.56%)	
occurrences (all)	10	2	
Weight decreased			
subjects affected / exposed	7 / 156 (4.49%)	3 / 78 (3.85%)	
occurrences (all)	7	3	
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	4 / 156 (2.56%)	1 / 78 (1.28%)	
occurrences (all)	4	1	
Headache			
subjects affected / exposed	39 / 156 (25.00%)	22 / 78 (28.21%)	
occurrences (all)	39	28	
Dizziness			
subjects affected / exposed	12 / 156 (7.69%)	6 / 78 (7.69%)	
occurrences (all)	14	6	
Dysgeusia			
subjects affected / exposed	8 / 156 (5.13%)	4 / 78 (5.13%)	
occurrences (all)	8	4	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	30 / 156 (19.23%)	8 / 78 (10.26%)	
occurrences (all)	37	9	
Neutropenia			
subjects affected / exposed	18 / 156 (11.54%)	12 / 78 (15.38%)	
occurrences (all)	29	19	
Thrombocytopenia			
subjects affected / exposed	4 / 156 (2.56%)	3 / 78 (3.85%)	
occurrences (all)	5	3	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	4 / 156 (2.56%)	3 / 78 (3.85%)	
occurrences (all)	4	3	
Eye disorders			

Ocular icterus subjects affected / exposed occurrences (all)	8 / 156 (5.13%) 8	0 / 78 (0.00%) 0	
Dry eye subjects affected / exposed occurrences (all)	6 / 156 (3.85%) 6	5 / 78 (6.41%) 5	
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	8 / 156 (5.13%) 9	2 / 78 (2.56%) 2	
Constipation subjects affected / exposed occurrences (all)	14 / 156 (8.97%) 16	3 / 78 (3.85%) 3	
Abdominal pain upper subjects affected / exposed occurrences (all)	16 / 156 (10.26%) 16	4 / 78 (5.13%) 4	
Diarrhoea subjects affected / exposed occurrences (all)	45 / 156 (28.85%) 52	10 / 78 (12.82%) 11	
Dyspepsia subjects affected / exposed occurrences (all)	13 / 156 (8.33%) 14	6 / 78 (7.69%) 6	
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	3 / 156 (1.92%) 3	5 / 78 (6.41%) 5	
Nausea subjects affected / exposed occurrences (all)	78 / 156 (50.00%) 82	18 / 78 (23.08%) 20	
Vomiting subjects affected / exposed occurrences (all)	41 / 156 (26.28%) 52	5 / 78 (6.41%) 6	
Hepatobiliary disorders			
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	11 / 156 (7.05%) 11	0 / 78 (0.00%) 0	
Jaundice			

subjects affected / exposed occurrences (all)	29 / 156 (18.59%) 29	1 / 78 (1.28%) 1	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	16 / 156 (10.26%)	4 / 78 (5.13%)	
occurrences (all)	16	4	
Dry skin			
subjects affected / exposed	29 / 156 (18.59%)	12 / 78 (15.38%)	
occurrences (all)	29	12	
Erythema			
subjects affected / exposed	8 / 156 (5.13%)	4 / 78 (5.13%)	
occurrences (all)	9	5	
Pruritus			
subjects affected / exposed	54 / 156 (34.62%)	23 / 78 (29.49%)	
occurrences (all)	58	23	
Rash			
subjects affected / exposed	37 / 156 (23.72%)	16 / 78 (20.51%)	
occurrences (all)	39	18	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	14 / 156 (8.97%)	8 / 78 (10.26%)	
occurrences (all)	15	8	
Arthralgia			
subjects affected / exposed	14 / 156 (8.97%)	7 / 78 (8.97%)	
occurrences (all)	14	7	
Myalgia			
subjects affected / exposed	20 / 156 (12.82%)	8 / 78 (10.26%)	
occurrences (all)	20	8	
Muscle spasms			
subjects affected / exposed	7 / 156 (4.49%)	2 / 78 (2.56%)	
occurrences (all)	9	2	
Infections and infestations			
Influenza			
subjects affected / exposed	4 / 156 (2.56%)	4 / 78 (5.13%)	
occurrences (all)	5	4	
Nasopharyngitis			

subjects affected / exposed occurrences (all)	14 / 156 (8.97%) 16	7 / 78 (8.97%) 9	
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	33 / 156 (21.15%) 34	10 / 78 (12.82%) 11	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 June 2011	<p>Revision of Cohort 2 (partial responders) and Cohort 3 (null responders) to contain a maximum of 250 patients each. Several time window changes to offer sites and patients more scheduling flexibility Clarification of definitions for severity of rash and management guidelines for rash/photosensitivity reactions Clarification of genotypic resistance section Clarification of End of Treatment; patients were not stopped early if their viral load was below the limit of quantification. Clarification of inclusion (i.e. liver diseasebiopsies sought but were allowed to be waived if patient would have been put at risk) Clarifications of exclusion criteria for criterion #2, as well as based on CTP classification and updates of the Summary of Product Characteristics (SPC) for ribavirin. Changes included: incidental steatosis diagnosed by biopsy was not an exclusion criterion, decompensated liver disease was based on CTP classification, pre-existing psychiatric conditions, added creatinine clearance ≤ 50 mL/min) Addition of section on pure red-cell aplasia to facilitate safety reporting Implementation of a revised AE grading system (DAIDS grading) in order to harmonize AE reporting across HCV projects. Adjusted definition and reporting of AEs of special interest Addition of HCRU and work productivity data collection for HEOR evaluation Clarification of management of missed treatment doses Patients that permanently discontinue any study drug were not eligible to stop all treatment at Week 24, but rather followed the 48-week visit schedule.Revision of other endpoints: Extended rapid virological response was removed and progression of liver disease following EOT was added. Clarification that not every severe or serious AE prompted treatment discontinuation.</p>
12 March 2012	<p>Modified duration of treatment to SVR12 as primary endpoint and SVR24 as secondary based on regulatory presentations and retrospective analysis of phase II data indicating 98% positive predictive value. Clarification of stopping rule: Viral load results obtained at Visit 2a (Day 2) and Visit 2b (Day 7) were used for correlation with PK levels only. Stopping rule criteria were not considered based on viral load values from Visit 2a and 2b. Clarification of process: Investigators remained blinded to HCV load results during the first 8 weeks of therapy. The Investigator was informed by IVRS when a criteria for treatment discontinuation due to lack of efficacy were met for a given patient during the first 8 weeks of treatment. Once at Week 12 (V6), investigators received HCV RNA results. Clarification of dose modifications: FDV except for the results prior to Week 12 which remained blinded: No dose reductions were permitted for FDV. Interruptions had to be discussed with the clinical monitor. If only FDV was discontinued, patient was continued on PegIFN and RBV if medically appropriate. FDV monotherapy was not allowed. PegIFN: Dose reduction PegIFN (according to ANC or platelets) was initiated as per protocol. If Peg IFN had to be permanently discontinued, RBV and FDV (if applicable) had to also be discontinued within 7 days from the final decision to discontinue PegIFN. PegIFN interruptions had to be discussed with the clinical monitor. RBV: Treatment visit change: Follow Up 2 Visit changed from ± 14 days to ± 7 days. Revision of EOT process to: The Week 48 visit was also performed for early treatment discontinuation patients as per schedule. Any patient who was virologic failure (lack of efficacy) and was eligible for the rollover trial (PegIFN/RBV failures) but refused participation in 1220.48 was discontinued from the trial. Follow up 2 visit window reduced to encourage more timely visits near database lock. Oral antivirals for herpes simplex were allowed.</p>

21 March 2012	Revised approach for implementation of amendment 2 to implement immediately to eliminate hazard and notify IRB/IEC/Competent Authority.
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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.

Due to the platform limitations, statistical analysis for null responders compared to historical rates of SVR could not be presented. Results for those can be found on ct.gov, study number NCT01358864.

Notes: