Clinical trial results:
A phase III, randomised, open label, active-controlled study of an interferon-free regimen of BI 207127 in combination with Faldaprevir and Ribavirin compared to Telaprevir in combination with pegylated interferon-a and ribavirin in treatment-naive patients with chronic genotype 1b Hepatitis C Virus infection.

Summary

EudraCT number	2012-004544-30
Trial protocol	BE SE NO IT GB ES DE DK FR
Global end of trial date	08 April 2013

Results information

Result version number	v1 (current)
This version publication date	08 July 2018
First version publication date	08 July 2018
Summary attachment (see zip file)	Statement (1241.37_Statement_Eudract.pdf)

Trial information

Trial identification

Sponsor protocol code	1241.37

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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 8002430127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	QRPE Processes and Systems Coordination, Clinical Trial Information Disclosure, Boehringer Ingelheim, +1 8002430127, clintriage.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 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 April 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 April 2013
Global end of trial reached?	Yes
Global end of trial date	08 April 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial is to determine if BI207127 + Faldaprevir + Ribavirin for 24 weeks is non-inferior to treatment with telaprevir for 12 weeks + Ribavirin and Pegylated interferon for 24 or 48 weeks.

Protection of trial subjects:

No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 April 2013
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	Norway: 99999
Country: Number of subjects enrolled	Spain: 99999
Country: Number of subjects enrolled	Belgium: 99999
Worldwide total number of subjects	299997
EEA total number of subjects	299997

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)	99999
From 65 to 84 years	99999

85 years and over	99999

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial

Pre-assignment

Screening details:

All subjects had to be screened for eligibility to participate in the trial. Subjects had to attend specialist sites which would then ensure that they (the subjects) met all 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	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Treatment assignment is blinded to the Investigator until after the patient has committed to participation. Upon randomization, the Investigator and patient will be made aware of the open label treatment assignment.

Arms

Are arms mutually exclusive?	Yes
Arm title	Faldaprevir

Arm description:

Patients were to be administered Soft gelatin capsule of Faldaprevir (First day 240 mg, then 120 mg) once daily for 16 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:

First day 240 mg, then 120 mg once daily for 16 weeks

Arm title	BI 207127

Arm description:

Patients were administered Film-coated tablets of BI 207127 (1200 mg (600mg twice daily (BID))) for 16 weeks

Arm type	Experimental
Investigational medicinal product name	BI 207127
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

(1200 mg (600mg twice daily (BID))) for 16 weeks

Arm title	Telaprevir tablets

Arm description:

Patients were administered Film-coated tablet 375 mg twice a day (3 tablets every 12 hours) for 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Telaprevir (Incivo®)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

375 mg Twice a day (3 tablets every 12 hours) for 12 weeks

Number of subjects in period 1	Faldaprevir	BI 207127	Telaprevir tablets
Started	99999	99999	99999
Completed	99999	99999	99999

Baseline characteristics

Reporting groups	
Reporting group title	Faldaprevir
Reporting group description:	
Patients were to be administered Soft gelatin capsule of Faldaprevir (First day 240 mg, then 120 mg) once daily for 16 weeks	
Reporting group title	BI 207127
Reporting group description:	
Patients were administered Film-coated tablets of BI 207127 (1200 mg (600mg twice daily (BID))) for 16 weeks	
Reporting group title	Telaprevir tablets
Reporting group description:	
Patients were administered Film-coated tablet 375 mg twice a day (3 tablets every 12 hours) for 12 weeks.	

Reporting group values	Faldaprevir	BI 207127	Telaprevir tablets
Number of subjects	99999	99999	99999
Age categorical Units: Subjects			
Age continuous			
Discontinued by Boehringer Ingelheim during preparation of trial. No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.			
Units: years arithmetic mean standard deviation	 0 ± 0	 0 ± 0	 0 ± 0
Gender categorical			
Discontinued by Boehringer Ingelheim during preparation of trial. No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.			
Units: Subjects			
Female	99999	99999	99999
Male	0	0	0

Reporting group values	Total		
Number of subjects	299997		
Age categorical Units: Subjects			
Age continuous			
Discontinued by Boehringer Ingelheim during preparation of trial. No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.			
Units: years arithmetic mean standard deviation	 -		

Gender categorical			
Discontinued by Boehringer Ingelheim during preparation of trial. No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.			
Units: Subjects			
Female	299997		
Male	0		

End points

End points reporting groups

Reporting group title	Faldaprevir
Reporting group description:	
Patients were to be administered Soft gelatin capsule of Faldaprevir (First day 240 mg, then 120 mg) once daily for 16 weeks	
Reporting group title	BI 207127
Reporting group description:	
Patients were administered Film-coated tablets of BI 207127 (1200 mg (600mg twice daily (BID))) for 16 weeks	
Reporting group title	Telaprevir tablets
Reporting group description:	
Patients were administered Film-coated tablet 375 mg twice a day (3 tablets every 12 hours) for 12 weeks.	

Primary: Sustained Virological response (SVR) at Week 12 post-treatment (SVR12)

End point title	Sustained Virological response (SVR) at Week 12 post-treatment (SVR12)[1]
End point description:	
SVR at Week 12 post-treatment (SVR12): Plasma HCV RNA level <25 IU/mL at 12 weeks after End of Treatment (EOT) Discontinued by Boehringer Ingelheim during preparation of trial. No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.	
End point type	Primary
End point timeframe:	
Week 12	
Notes:	
[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: No subjects were enrolled in the trial hence results are not available	

End point values	Faldaprevir	BI 207127	Telaprevir tablets	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	99999[2]	99999[3]	99999[4]	
Units: percentage of participants	99999	99999	99999	

Notes:

[2] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

[3] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

[4] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

Statistical analyses

No statistical analyses for this end point

Secondary: SVR at Week 4 post-treatment (SVR4):

End point title	SVR at Week 4 post-treatment (SVR4):

End point description:

SVR4: Plasma HCV RNA level <25 IU/mL at 4 weeks after EOT.
No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

End point type	Secondary

End point timeframe:

Week 4

End point values	Faldaprevir	BI 207127	Telaprevir tablets	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	99999[5]	99999[6]	99999[7]	
Units: percentage of participants	99999	99999	99999	

Notes:

[5] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

[6] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

[7] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

Statistical analyses

No statistical analyses for this end point

Secondary: SVR24: Plasma HCV RNA level <25 IU/mL at 24 weeks after EOT.

End point title	SVR24: Plasma HCV RNA level <25 IU/mL at 24 weeks after EOT.

End point description:

SVR24: Plasma HCV RNA level <25 IU/mL at 24 weeks after EOT.
No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

End point type	Secondary

End point timeframe:

Week 24

End point values	Faldaprevir	BI 207127	Telaprevir tablets	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	99999[8]	99999[9]	99999[10]	
Units: percentage of participants	99999	99999	99999	

Notes:

[8] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

[9] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

[10] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

Statistical analyses

No statistical analyses for this end point

Secondary: Adverse Events (AEs), Serious Adverse Events (SAEs), lab values

End point title	Adverse Events (AEs), Serious Adverse Events (SAEs), lab

	values

End point description:

Adverse Events (AEs), Serious Adverse Events (SAEs), lab values.
No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

End point type	Secondary

End point timeframe:

All adverse events, serious and non-serious, with an onset date from signing the informed consent up to follow up visit (28 days after all treatment discontinuation); up to 52 weeks

End point values	Faldaprevir	BI 207127	Telaprevir tablets	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	99999[11]	99999[12]	99999[13]	
Units: percentage of participants	99999	99999	99999	

Notes:

[11] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

[12] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

[13] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All adverse events, serious and non-serious, with an onset date from signing the informed consent up to follow up visit (28 days after all treatment discontinuation); up to 52 weeks

Adverse event reporting additional description:

No patient entered the study, therefore no results data available.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No subjects were enrolled in the trial hence results are not available

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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.

Discontinued by Boehringer Ingelheim during initiation of the trial. No patient entered the study, therefore no results / data are available.

Notes: