Clinical trial results:
A Phase 3 Study to Assess the Efficacy and Safety of Boceprevir in Combination With Peginterferon Alfa-2b Plus Ribavirin in Pediatric Subjects With Chronic Hepatitis C Genotype 1

Summary

EudraCT number	2010-024260-17
Trial protocol	DE AT BE PT CZ ES IT PL NO GB
Global end of trial date	21 January 2014
Results information	
Result version number	v1 (current)
This version publication date	17 August 2020
First version publication date	17 August 2020
Summary attachment (see zip file)	EudraCT Summary Results (P08034_2019-05-17_Cancelled_Withdrawn Memo for EU CTR.docx) Cancelled/Withdrawn Memo (MK-3034-043_P08034_2020-07-30_EudraCT_Cancelled_Withdrawn Memo for EU CTR.docx)

Trial information

Trial identification	
Sponsor protocol code	P08034
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01590225
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States,
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com

Notes:

Paediatric regulatory details	
Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-099999-PIP99-99
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	21 January 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 January 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

This trial was to be a three-part (Part A, Part B, and Part C), open-label, multicenter study of boceprevir in pediatric participants with chronic hepatitis C (CHC) genotype 1 (GT1). In Part A and Part B, efficacy and safety were to be evaluated in participants with CHC GT1 who are non-cirrhotic, treatment naïves (Part A) or who are non-cirrhotic, treatment failures to (peg)interferon/ribavirin or who are cirrhotics (whether treatment naïve or treatment failure) (Part B). Part C was to be a long-term follow up and no study treatment was to be administered during this period, but participants who did not achieve viral clearance were to going to be allowed to receive other treatments for CHC.

Note: This study was withdrawn. No participants were ever enrolled in it.

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 January 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Note: This trial was withdrawn. No participants were ever enrolled in it.

Pre-assignment

Screening details:

N/A

Period 1

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

Arms

Arm title	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Boceprevir
Investigational medicinal product code	
Other name	Victrelis® SCH 503034
Pharmaceutical forms	Capsule, Granules in sachet
Routes of administration	Oral use

Dosage and administration details:

Boceprevir will be administered orally at a dose of 11.4 mg/kg three-times daily (TID) for 48 weeks. The boceprevir dose will be calculated based on 11.4 mg/kg and will then be rounded to the nearest 200-mg value for participants in the oldest age group, or to the nearest 100-mg or 200-mg value for the participants in the two youngest age groups.

Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	Copegus® Rebetol® RibaTab® Ribasphere®
Pharmaceutical forms	Capsule, Oral solution
Routes of administration	Oral use

Dosage and administration details:

The dose of ribavirin will be approximately 15 mg/kg/day administered orally in two divided doses (twice daily [BID]) for 48 weeks.

Investigational medicinal product name	Peginterferon alpha-2b
Investigational medicinal product code	
Other name	Pegintron® Sylatron®
Pharmaceutical forms	Concentrate and solvent for solution for infusion, Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Peginterferon alpha-2b will be administered subcutaneously at a dose of 60 µg/m^2 once weekly (QW) for 48 weeks.

Number of subjects in period 1	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin

Reporting group description: -

Reporting group values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin	Total	
Number of subjects	99999	99999	
Age Categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	99999	99999	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous Units: years			
arithmetic mean	0		
full range (min-max)	0 to 0	-	
Gender Categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin

Reporting group description: -

Primary: Participants Achieving Sustained Viral Response (SVR) at Follow-Up Week 24

End point title	Participants Achieving Sustained Viral Response (SVR) at Follow-Up Week 24[1]

End point description:

End point type	Primary

End point timeframe:

Follow-Up Week 24

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: Note: This study was withdrawn. No participants were ever enrolled in it.

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: Participants				

Notes:

[2] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Primary: Participants Achieving SVR at Follow-Up Week 24

End point title	Participants Achieving SVR at Follow-Up Week 24[3]

End point description:

End point type	Primary

End point timeframe:

Follow-Up Week 24

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Note: This study was withdrawn. No participants were ever enrolled in it.

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[4]			
Units: Participants				

Notes:

[4] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Primary: Time to Viral Relapse in Study Part C: Long-Term Follow Up

End point title	Time to Viral Relapse in Study Part C: Long-Term Follow Up[5]

End point description:

End point type	Primary

End point timeframe:

Follow-Up Week 24 to 5 Years

Notes:

[5] - 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: Note: This study was withdrawn. No participants were ever enrolled in it.

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[6]			
Units: Years				

Notes:

[6] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Participants With Alanine Aminotransferase (ALT) Normalization

End point title	Proportion of Participants With Alanine Aminotransferase (ALT) Normalization

End point description:

End point type	Secondary

End point timeframe:

Week 2, Week 4, Week 8, Week 12

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[7]			
Units: Proportion of Participants				

Notes:

[7] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Participants With Early Virologic Response

End point title	Participants With Early Virologic Response

End point description:

End point type	Secondary

End point timeframe:

Week 2, Week 4, Week 8, Week 12

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[8]			
Units: Participants				

Notes:

[8] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Participants With Undetectable Hepatitis C Virus Ribonucleic Acid (HCV-RNA)

End point title	Proportion of Participants With Undetectable Hepatitis C Virus Ribonucleic Acid (HCV-RNA)

End point description:

End point type	Secondary

End point timeframe:

Week 12, End of Treatment, Follow-Up Week 24

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[9]			
Units: Percentage of participants				

Notes:

[9] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Participants With Undetectable HCV-RNA Who Also Achieved SVR

End point title	Proportion of Participants With Undetectable HCV-RNA Who Also Achieved SVR

End point description:

End point type	Secondary

End point timeframe:

Follow-Up Week 12

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[10]			
Units: Percentage of participants				

Notes:

[10] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Participants With Alanine Aminotransferase (ALT) Normalization in Study

End point title	Proportion of Participants With Alanine Aminotransferase (ALT) Normalization in Study

End point description:

End point type	Secondary

End point timeframe:
Week 2, Week 4, Week 8, Week 12

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[11]			
Units: Percentage of participants				

Notes:
[11] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Participants With Undetectable HCV-RNA

End point title	Proportion of Participants With Undetectable HCV-RNA

End point description:

End point type	Secondary

End point timeframe:
Week 24, End of Treatment, Follow-Up Week 12

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[12]			
Units: Percentage of participants				

Notes:
[12] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Participants With Undetectable HCV-RNA Who Also Achieved SVR

End point title	Proportion of Participants With Undetectable HCV-RNA Who Also Achieved SVR

End point description:

End point type	Secondary

End point timeframe:
Follow-Up Week 12

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[13]			
Units: Percentage of participants				

Notes:
[13] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Experiencing Treatment-Emergent Adverse Events (AEs)

End point title	Number of Participants Experiencing Treatment-Emergent Adverse Events (AEs)

End point description:

End point type	Secondary

End point timeframe:
Week 1 to Follow-Up Visit 24

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[14]			
Units: Participants				

Notes:
[14] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Experiencing Treatment-Emergent Treatment-Related AEs

End point title	Number of Participants Experiencing Treatment-Emergent Treatment-Related AEs

End point description:

End point type	Secondary

End point timeframe:

Week 1 to Follow-Up Week 24

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[15]			
Units: Participants				

Notes:

[15] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Experiencing Serious AEs (SAEs)

End point title	Number of Participants Experiencing Serious AEs (SAEs)

End point description:

End point type	Secondary

End point timeframe:

Week 1 to Follow-Up Week 24

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[16]			
Units: Participants				

Notes:

[16] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Discontinuing Treatment Due to AEs

End point title	Number of Participants Discontinuing Treatment Due to AEs

End point description:

End point type	Secondary

End point timeframe:

Week 1 to Follow-Up Week 24

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[17]			
Units: Participants				

Notes:

[17] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Participant Laboratory Values

End point title	Change from Baseline in Participant Laboratory Values

End point description:

End point type	Secondary

End point timeframe:

Baseline to Follow-Up Week 24

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[18]			
Units: Number				

Notes:

[18] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Experiencing AEs

End point title	Number of Participants Experiencing AEs

End point description:

End point type	Secondary

End point timeframe:

Week 1 to Follow-Up Week 24

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[19]			
Units: Participants				

Notes:

[19] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Participant Vital Signs

End point title	Change From Baseline in Participant Vital Signs

End point description:

End point type	Secondary

End point timeframe:

Week 1 to Follow-Up Week 24

End point values	Part A and B: boceprevir + peginterferon alpha-2b + ribavirin			
Subject group type	Reporting group			
Number of subjects analysed	0[20]			
Units: Number				

Notes:

[20] - Note: This study was withdrawn. No participants were ever enrolled in it.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All adverse events occurring during the course of the clinical trial were to be collected.

Adverse event reporting additional description:

99999 is a "Not applicable" value. There were 0 participants. This study was withdrawn. No participants were ever enrolled in it.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Reporting groups

Reporting group title	Part A: boceprevir + peginterferon alpha-2b + ribavirin

Reporting group description: -

Reporting group title	Part B: boceprevir + peginterferon alpha-2b + ribavirin

Reporting group description: -

Serious adverse events	Part A: boceprevir + peginterferon alpha-2b + ribavirin	Part B: boceprevir + peginterferon alpha-2b + ribavirin	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)	0 / 99999 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Part A: boceprevir + peginterferon alpha-2b + ribavirin	Part B: boceprevir + peginterferon alpha-2b + ribavirin	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)	0 / 99999 (0.00%)	

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: Note: This study was withdrawn. No participants were ever enrolled in it.

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.

Note: This study was withdrawn. No participants were ever enrolled in it.

Notes: