Clinical trial results:
Response-guided triple therapy using boceprevir in combination with PEGIFN/RBV in HIV/HCV coinfected patients

Summary

EudraCT number	2012-005591-33
Trial protocol	AT
Global end of trial date	17 June 2015

Results information

Result version number	v1 (current)
This version publication date	29 December 2016
First version publication date	29 December 2016

Trial information

Trial identification

Sponsor protocol code	HIVCOBOC-RGT

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01925183
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Medizinische Universität Wien
Sponsor organisation address	Währinger Gürtel 18-20, Wien, Austria, 1090
Public contact	Verantwortlicher Prüfer, Medizinische Universität Wien, +43 14040047440, markus.peck@meduniwien.ac.at
Scientific contact	Verantwortlicher Prüfer, Medizinische Universität Wien, +43 14040047440, markus.peck@meduniwien.ac.at

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	17 June 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 June 2015
Global end of trial reached?	Yes
Global end of trial date	17 June 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary efficacy objective:
• to assess the rate of sustained virologic response (SVR12) at follow-up week 12 (FU12), which is defined as HCV-RNA negativity by a sensitive PCR assay

Primary safety/tolerability objective:
• to assess the rate of adverse events (AEs) and severe adverse events (SAEs)

Protection of trial subjects:

No specific measures.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 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	Austria: 6
Worldwide total number of subjects	6
EEA total number of subjects	6

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)	6
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Six patients patients were screened during the pre-assignment period (from 16-JUL-2013 to 31-JAN-2014) and six patients were recruited.

Pre-assignment

Screening details:

Six patients patients were screened during the pre-assignment period (from 16-JUL-2013 to 31-JAN-2014).

Period 1

Period 1 title	Treatment period and follow-up (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not blinded

Arms

Arm title	HIVCOBOC-RGT

Arm description:

Response-guided triple therapy using boceprevir in combination with PEGIFN/RBV

Arm type	Experimental
Investigational medicinal product name	Victrelis
Investigational medicinal product code	SUB31579
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

2400 mg milligram(s) per day

Number of subjects in period 1	HIVCOBOC-RGT
Started	6
Completed	6

Baseline characteristics

Reporting groups

Reporting group title	HIVCOBOC-RGT

Reporting group description:

Response-guided triple therapy using boceprevir in combination with PEGIFN/RBV

Reporting group values	HIVCOBOC-RGT	Total	
Number of subjects	6	6	
Age categorical Units: Subjects			
Adults (18-64 years)	6	6	
Gender categorical Units: Subjects			
Female	1	1	
Male	5	5	

Subject analysis sets

Subject analysis set title	Intention-to-treat
Subject analysis set type	Intention-to-treat

Subject analysis set description:

This analysis set includes subject all study subject that received at least one dose of the study drug.

Reporting group values	Intention-to-treat		
Number of subjects	6		
Age categorical Units: Subjects			
Adults (18-64 years)	6		
Gender categorical Units: Subjects			
Female	1		
Male	5		

End points

End points reporting groups

Reporting group title	HIVCOBOC-RGT
Reporting group description:	
Response-guided triple therapy using boceprevir in combination with PEGIFN/RBV	
Subject analysis set title	Intention-to-treat
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
This analysis set includes subject all study subject that received at least one dose of the study drug.	

Primary: Primary efficacy endpoint: Sustained virologic response (SVR12)

End point title	Primary efficacy endpoint: Sustained virologic response (SVR12)
End point description:	
Defined as HCV-RNA negativity by a sensitive PCR assay	
End point type	Primary
End point timeframe:	
Follow-up week 12 (FU12)	

End point values	HIVCOBOC-RGT	Intention-to-treat		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	6	6		
Units: Number of patients	5	5		

Statistical analyses

Statistical analysis title	Descriptive statistics
Comparison groups	HIVCOBOC-RGT v Intention-to-treat
Number of subjects included in analysis	12
Analysis specification	Pre-specified
Analysis type	other[1]
Parameter estimate	Rate (percent)
Point estimate	83
Confidence interval	
level	95 %
sides	2-sided
lower limit	48
upper limit	98

Notes:

[1] - Descriptive statistics only.

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From baseline (BL) to the end of follow-up (FU24)	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups	
Reporting group title	HIVCOBOC-RGT
Reporting group description:	
Response-guided triple therapy using boceprevir in combination with PEGIFN/RBV	

Serious adverse events	HIVCOBOC-RGT		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Skin and subcutaneous tissue disorders			
Abscess soft tissue			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	HIVCOBOC-RGT		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)		
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 6 (66.67%)		
occurrences (all)	4		

Neutropenia			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Platelet count decreased			
subjects affected / exposed	5 / 6 (83.33%)		
occurrences (all)	5		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	5 / 6 (83.33%)		
occurrences (all)	5		
Influenza like illness			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Immune system disorders			
Psoriasis	Additional description: Psoriasis flare-up		
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Vomiting			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Diarrhoea			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Glossodynia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		

Toothache			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Dyspnoea			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Hair loss			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	3 / 6 (50.00%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		

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

None reported