Clinical trial results:
A Randomized, Global, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Vedolizumab IV for the Treatment of Primary Sclerosing Cholangitis, With Underlying Inflammatory Bowel Disease

Summary

EudraCT number	2014-003942-28
Trial protocol	ES BE GB HU SE DE CZ AT PL FR IT
Global end of trial date	23 February 2017

Results information

Result version number	v1 (current)
This version publication date	13 September 2020
First version publication date	13 September 2020

Trial information

Trial identification

Sponsor protocol code	MLN0002-3023

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03035058
WHO universal trial number (UTN)	U1111-1161-4900
Other trial identifiers	NL56650.056.16: CCMO, 16/LO/0288: NRES, 191059: HC-CTD

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	One Takeda Parkway, Deerfield, United States, 60015
Public contact	Medical Director, Clinical Science, Takeda Development Centre Europe, Ltd., +44 1256 894003,
Scientific contact	Medical Director, Clinical Science, Takeda Development Centre Europe, Ltd., +44 1256 894003,

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	23 February 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 February 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the efficacy and safety of vedolizumab intravenous (IV) in non–end-stage primary sclerosing cholangitis (PSC) participants with underlying inflammatory bowel disease (IBD).

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 February 2017
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	France: 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)	0
Adults (18-64 years)	99999
From 65 to 84 years	0
85 years and over	0

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:

N/A

Period 1

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

Arms

Arm title	Overall

Arm description:

Vedolizumab 300 mg, intravenous (IV)

Arm type	Experimental
Investigational medicinal product name	Vedolizumab IV
Investigational medicinal product code	MLN0002
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Dosage would have been once at Day 1 and Week 2 then once every 4 weeks from Week 6 to Week 102.

Number of subjects in period 1	Overall
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Overall
Reporting group description:	
Vedolizumab 300 mg, intravenous (IV)	

Reporting group values	Overall	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)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Overall
Reporting group description: Vedolizumab 300 mg, intravenous (IV)	

Primary: Percentage of Participants with No Worsening in Ishak Fibrosis Staging Score from Baseline to Week 106 Visit

End point title	Percentage of Participants with No Worsening in Ishak Fibrosis Staging Score from Baseline to Week 106 Visit[1]

End point description:

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:

N/A

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses have been specified for this primary end point.

End point values	Overall			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: number	99999			

Notes:

[2] - No subjects were enrolled in the trial hence results are not available

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:

N/A

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Reporting groups

Reporting group title	Vedolizumab

Reporting group description:

Vedolizumab 300 mg IV

Serious adverse events	Vedolizumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Vedolizumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	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: There are no non-serious adverse events recorded for these results.

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.

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

Notes: