



Clinical trial results:

Phase II, Randomized, Double-Blind, Placebo-Controlled, Proof-of-Concept Study to Evaluate the Efficacy, Safety, Tolerability, and Pharmacokinetics of GLPG1205 in Patients With Moderate Crohn's Disease

Summary

EudraCT number	2014-001892-30
Trial protocol	HU BE
Global end of trial date	09 December 2014

Results information

Result version number	v1 (current)
This version publication date	16 October 2020
First version publication date	16 October 2020
Summary attachment (see zip file)	Cancelled before enrollment statement (glpg1205-cl-201-synopsis.pdf)

Trial information

Trial identification

Sponsor protocol code	GLPG1205-CL-201
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Galapagos NV
Sponsor organisation address	Generaal De Wittelaan L11 A3, Mechelen, Belgium, 2800
Public contact	Medical Information, Galapagos NV, +32 15342900, medicalinfo@glpg.com
Scientific contact	Clinical Trial Information Desk, Galapagos NV, +32 15342900, rd@glpg.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	09 December 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	09 December 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate efficacy in terms of the change in Crohn's Disease Activity Index (CDAI) score compared with baseline following 12 weeks of treatment with GLPG1205 100 mg once daily (qd) versus placebo in subjects with active moderate Crohn's Disease (CD).

Protection of trial subjects:

This study will be conducted in accordance with the current ICH-GCP Guideline E6. Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of study subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical study data are credible.

The investigator or designated personnel must explain the study and the implications of participation (e.g., objectives, methods, anticipated benefits, and possible risks) to potential subjects according to local regulations prior to any trial related activity. Subjects will be informed that their participation is voluntary and that they may withdraw from the study at any time. They will be informed that choosing not to participate or to withdraw from the study will not have an impact on the care the subject will receive for the treatment of his/her disease. In case the subject is unable to read and write, an impartial witness must confirm the informed consent.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 November 2014
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	Belgium: 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	Not applicable
Blinding used	Not blinded

Blinding implementation details:

N/A

Arms

Arm title	GLPG1205
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	GLPG1205
Investigational medicinal product code	G321605
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects will receive 100 mg GLPG1205 (2 capsules of 50 mg) or placebo qd for 12 weeks. The GLPG1205 or placebo capsules should be taken orally with a glass of water in the morning. Subjects will be instructed to swallow the study drug whole, and not chew the drug prior to swallowing.

Number of subjects in period 1	GLPG1205
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Overall Trial
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Reporting group description: -

Reporting group values	Overall Trial	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	GLPG1205
Reporting group description:	-

Primary: CDAI baseline score

End point title	CDAI baseline score ^[1]
End point description:	Difference in CDAI change from baseline between GLPG1205- and placebo-treated subjects at Week 12.
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 subjects were enrolled in the trial hence results are not available.

End point values	GLPG1205			
Subject group type	Reporting group			
Number of subjects analysed	99999 ^[2]			
Units: Subjects				
number (not applicable)	0			

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:

From first study drug administration until the last follow-up visit.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	0
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Reporting groups

Reporting group title	GLPG1205
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Reporting group description:

GLPG1205 Dose A

Serious adverse events	GLPG1205		
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: 0 %

Non-serious adverse events	GLPG1205		
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: 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.

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

Notes: