Clinical trial results:
A Phase II, randomized, double-blind, placebo-controlled, multi-center study to evaluate the efficacy, safety, tolerability and pharmacokinetics of orally administered combination of GLPG3067, GLPG2222 and GLPG2737, in adult subjects with cystic fibrosis homozygous or heterozygous for F508del CFTR.

Summary

EudraCT number	2018-000098-61
Trial protocol	GB
Global end of trial date	17 July 2018

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 (glpg3067-cl-202-synopsis.pdf)

Trial information

Trial identification

Sponsor protocol code	GLPG3067-CL-202

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 15342 900, medicalinfo@glpg.com
Scientific contact	Clinical Trial Information Desk, Galapagos NV, +32 15342 900, 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	17 July 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 July 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess changes in sweat chloride concentration as a biomarker of CFTR ion channel function for dual combination (GLPG3067 and GLPG2222) and triple combination (GLPG3067, GLPG2222, and GLPG2737) treatment, in adult CF subjects who are homozygous for CFTR mutation F508del, and in adult CF subjects who are heterozygous for CFTR mutation F508del (with a mutation on the second allele, which is non-responsive to potentiator).

Protection of trial subjects:

This clinical study will be conducted in accordance with the current International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP) Guideline E6.

The investigator or designated personnel must explain the clinical study and the implications of participation (e.g., objectives, methods, anticipated benefits, and possible risks) to potential subjects according to applicable regulations prior to any clinical study related activity. Subjects will be informed that their participation is voluntary and that they may withdraw from the clinical study at any time. They will be informed that choosing not to participate or to withdraw from the clinical 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	02 July 2018
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	United Kingdom: 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	Double blind
Roles blinded	Investigator, Subject, Monitor, Data analyst, Carer, Assessor

Arms

Arm title	Part I

Arm description:

F508del homozygous

Arm type	Experimental
Investigational medicinal product name	GLPG3067
Investigational medicinal product code	G914167
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Not applicable due to trial discontinuation.

Investigational medicinal product name	GLPG2222
Investigational medicinal product code	G957389
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Not applicable due to trial discontinuation.

Investigational medicinal product name	GLPG2737
Investigational medicinal product code	G1117337
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Not applicable due to trial discontinuation.

Number of subjects in period 1	Part I
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Overall Trial

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	Part I
Reporting group description:	
F508del homozygous	

Primary: Change from baseline in sweat chloride concentration

End point title	Change from baseline in sweat chloride concentration[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 subjects were enrolled in the trial hence results are not available .

End point values	Part I			
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 their follow-up visit.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Reporting groups

Reporting group title	Part I

Reporting group description: -

Serious adverse events	Part I		
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	Part I		
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: 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

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: