A Phase I, open-label study to investigate the pharmacokinetics of GLPG2451 given as two doses of a capsule formulation in healthy subjects

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PRIMARY OBJECTIVES- To investigate the PK profile of GLPG2451 administered as two doses of a capsule formulation in healthy subjects.- To assess the safety and tolerability of GLPG2451 administered as two doses of a capsule formulation in healthy…

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45502

Source
ToetsingOnline

Brief title
Pharmacokinetics study of GLPG2451 in healthy subjects

Condition

- Other condition
- Congenital and hereditary disorders NEC

Synonym
Cystic fibrosis; mucoviscidosis; thick mucus disease

Health condition

Cystic fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Galapagos SASU
Source(s) of monetary or material Support: Galapagos SASU

Intervention

Keyword: Cystic fibrosis, GLGP2451, Pharmacokinetics

Outcome measures

Primary outcome

- Determine PK parameters of GLPG2451 in plasma (including Cmax, AUC)

administered as two doses of a capsule formulation in healthy subjects.

- Determine safety and tolerability of GLPG2451 in healthy subjects, assessed

by the number of subjects with AEs.

Secondary outcome

SECONDARY ENDPOINT

- Determine PK parameters of G1171564 (metabolite of GLPG2451) in plasma.

Study description

Background summary

Cystic fibrosis (CF) is caused by mutations in the gene encoding for the cystic fibrosis transmembrane conductance regulator (CFTR) protein, a cyclic adenosine monophosphate (cAMP)-regulated anion channel expressed primarily at the apical plasma membrane of secretory epithelia. Over 2,000 mutations in the CFTR gene (CFTR) have been identified, which are grouped into six classes (Class I-VI).
The F508del mutation is by far the most common CFTR mutation globally, especially in the Caucasian population. Approximately 80 to 90% of CF patients in the United States and Europe have at least one copy of this mutation on one allele, with almost half of them being F508del homozygous (i.e. the mutation is present on both alleles). The F508del mutation impairs CFTR folding,

trafficking towards the plasma membrane, has reduced plasma membrane stability, and has reduced chloride gating. Thus, patients with the F508del mutation have very little to no CFTR protein in the apical membrane. CFTR dysfunction results in viscid secretions that are difficult to clear, affecting most exocrine glands, notably in the pancreas, intestine, liver and bile duct. However, most morbidity and mortality results from dehydration of the airway surface liquid and impaired airway mucociliary clearance, which leads to cycles of bacterial infection, chronic inflammation, bronchiectasis and progressive decline in pulmonary function. There is a high medical need for adequate therapeutic approaches targeting the F508del mutation.

Study objective

PRIMARY OBJECTIVES
- To investigate the PK profile of GLPG2451 administered as two doses of a capsule formulation in healthy subjects.
- To assess the safety and tolerability of GLPG2451 administered as two doses of a capsule formulation in healthy subjects.
SECONDARY OBJECTIVE
- To investigate the PK profile of G1171564 (metabolite of GLPG2451).
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Study design

This study is a Phase I, open-label study to investigate the PK of GLPG2451 given as two doses (5 mg and 80 mg) of a capsule formulation

Intervention

1 dose of 5 mg GLPG2451 and after 14 days 1 dose of 80 mg GLPG2451

Study burden and risks

There is no direct benefit to you from taking part in the study. The results of the study will provide valuable information for future research.
Not all side effects of new compounds, such as GPLG2451 are known. Unexpected side effects might occur. GPLG2451 has been administered to humans before and has been investigated in laboratories and animal studies. During previous clinical studies with GLPG2451, the most frequently reported adverse events were: headache, common cold, shoulder pain, lumboschialgia, loose stools, decreased appetite, increased energy, sore throat and migraine headache.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male subject or female subject of non-childbearing potential between 18-50 years of age, inclusive, on the date of signing the informed consent form (ICF).
- Female subjects must be of non-childbearing potential defined as surgically sterile (hysterectomy, bilateral salpingectomy and bilateral oophorectomy), or post-menopausal (at least 12 consecutive months without menstruation, without an alternative medical cause [including hormone replacement therapy]).
- Have a body mass index between 18-30 kg/m2, inclusive.
- Judged by the investigator to be in good health based upon the results of a medical history, physical examination, vital signs, 12-lead ECG, and clinical safety laboratory tests prior to the initial study drug administration. Clinical safety laboratory test results must be within the laboratory reference ranges, or test results that are outside the reference ranges need to be considered non-clinically significant in the opinion of the investigator. One retest is allowed if

deemed appropriate by the investigator.
- Discontinuation of all medications (including over-the-counter and/or prescription medication, dietary supplements, nutraceuticals, vitamins and/or herbal supplements) except occasional paracetamol (maximum dose of 2 g/day and maximum of 10 g/2 weeks) at least 2 weeks prior to the first study drug administration.
- Able and willing to comply with the prohibitions and restrictions and with the contraceptive requirements (male subjects only), as described
in the protocol.
- Able and willing to sign the ICF as approved by the Independent Ethics Committee (IEC), prior to any screening evaluations.;Reference is made to the protocol for a complete overview of the inclusion criteria.

Exclusion criteria

- Known hypersensitivity to study drug ingredients or a significant allergic reaction to any drug as determined by the investigator, such as
anaphylaxis requiring hospitalization.
- Clinically significant symptoms or illness in the 3 months prior to screening.
- Presence or having sequelae of gastrointestinal, liver, kidney or other conditions known to interfere with the absorption, distribution,
metabolism, or excretion of drugs.
- Evidence of lens opacity on slit lamp examination or similar system.
- Significant blood loss (including blood donation [>500 mL]), or a transfusion of any blood product within 12 weeks prior to the first study
drug administration.
- Treatment with any drug known to have a well-defined potential for toxicity to a major organ in the last 3 months or 5 times the half-life of
the drug (whichever is longer) prior to the first study drug administration.
- Participation in a drug, drug and device delivery system or combination, or biologic investigational research study within 8 weeks or
5 times the half-life of the investigational drug, if the half-life is known (whichever is longer) prior to the first study drug administration.;Reference is made to the protocol for a complete overview of the exclusion criteria.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Not applicable
Generic name:	GLPG2451

Ethics review

Approved WMO Date:	25-04-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-05-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-000874-12-NL
CCMO	NL61239.056.17