A Phase 2 Study of ABBV-3067 Alone and in Combination with ABBV-2222 in Cystic Fibrosis Subjects Who Are Homozygous for the F508del Mutation

Published: 05-08-2019
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In Part 1 of the study, a fixed dose of ABBV-3067 (potentiator) will be co-administered with ABBV-2222 (corrector) in a dose range-finding manner to enable a dose selection for ABBV-2222 for Part 2 and future combination studies. In addition, ABBV-...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory disorders congenital
Study type	Interventional

Summary

ID

NL-OMON48171

Source
ToetsingOnline

Brief title
M19-530

Condition

- Respiratory disorders congenital

Synonym
CF, mucoviscidosis

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie Deutschland GmbH & Co. KG
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: Corrector, Cystic Fibrosis, Potentiator, Randomised

Outcome measures

Primary outcome

Change from Baseline through Day 29 in overall lung function.

Secondary outcome

1) Change from Baseline through Day 29 in sweat chloride

2) Change from Baseline through Day 29 in other spirometric measures

3) Change from Baseline through Day 29 in lung function

Study description

Background summary

Cystic fibrosis (CF) is a genetic disease that affects many organs including the lungs, in which sticky mucus and persistent infections cause increased breathing difficulty over time. CF is caused by mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that affect the production and function of the CFTR protein. When the CFTR protein is not produced correctly, it affects the balance of salt and fluids inside and outside of the cell. This imbalance leads to thick, sticky mucus in the lungs, and loss of organ functions in the pancreas and other organs. ABBV-3067 is a type of CFTR modulator called a potentiator. Potentiators help facilitate the opening of the CFTR protein on the cell surface to allow chloride and sodium (salt) to move in and out of the cell. ABBV-2222 is a CFTR corrector. Correctors help the CFTR protein form the right shape so that it can move to the cell surface.

Study objective

In Part 1 of the study, a fixed dose of ABBV-3067 (potentiator) will be

co-administered with ABBV-2222 (corrector) in a dose range-finding manner to enable a dose selection for ABBV-2222 for Part 2 and future combination studies. In addition, ABBV-3067 will be given alone (i.e. with placebo for ABBV-2222) to evaluate the safety and efficacy of ABBV-3067.
In Part 2 of the study, the dose of ABBV-2222 selected from Part 1 will be co-administered with ABBV-3067 in a dose-ranging manner to enable selection of the ABBV-3067 dose for future combination studies.

Study design

Randomised, double-blind, placebo controlled parallel arm study

Intervention

ABBV-3067 and/or ABBV-2222 in different doses, placebo controlled.

Study burden and risks

Risks associated with participation are risks involving study procedures and risks associated with the study drug.
The duration of participation can take up to three months, with a screening period, a treatment period and a follow up period. The participant will need to attend study visits and a phone call. The participant does not need to complete diaries or questionnaires.

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

*Adults 18 years or older
*Confirmed diagnosis of CF and homozygous for F508del CFTR mutation
*Lung function >= 40% and <= 90% of predicted normal for age, gender, and height
*Stable pulmonary status

Exclusion criteria

*Cirrhosis with portal hypertension
*History of solid organ or hematopoietic transplantation

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	4
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	ABBV-2222
Generic name:	Galicaftor
Product type:	Medicine
Brand name:	ABBV-3067
Generic name:	ABBV-3067

Ethics review

Approved WMO Date:	05-08-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-10-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-01-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-02-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-06-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	28-07-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-04-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-04-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2019-000750-63-NL
ClinicalTrials.gov	NCT03969888
CCMO	NL70226.041.19

Study results

Results posted: 11-07-2023

Summary results
Trial never started

URL result

URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File