A Randomized, Double-Blind, Placebo-Controlled, Phase 1, Single and Multiple Ascending Dose Study to Assess the Safety, Pharmacokinetics, Pharmacodynamics, and Food Effect of THB001 in Healthy Subjects

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21075

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Preliminary safety study, first in human.

Sponsors and support

Primary sponsor: Third Harmonic Bio.
Source(s) of monetary or material Support: Third Harmonic Bio.

Intervention

Outcome measures

Primary outcome

Safety and tolerability parameters for THB001 including: physical examination, AEs, clinical laboratory values, vital signs and ECGs. PK parameters for THB001

Secondary outcome

PK parameters for THB001

Study description

Background summary

This is a first-in-human study of THB001 conducted as a single ascending dose (SAD), food effect, and multiple ascending dose (MAD) evaluation of safety, tolerability, and pharmacokinetics in healthy volunteers

Study objective

Assess the safety and tolerability of single and multiple ascending doses of THB001 in addition to the effects of food in healthy volunteers.

Study design

Screening up to -28 days, treatment period up to 17 days and a follow-up period through 77 days

Intervention

THB001 or placebo

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

Subjects must understand the nature of the study and must provide signed and dated written informed consent in accordance with local regulations before the conduct of any study-related procedures.

Healthy as determined by the Investigator, based on a medical evaluation including medical history, physical examination, laboratory tests and ECG recording.

Men and women aged 18-65 years (inclusive) who meet all entry criteria.

Exclusion criteria

A history or presence of cancer or of a clinically significant hepatic, biliary, renal, gastrointestinal, cardiovascular, endocrine, pulmonary, ophthalmologic, immunologic, hematologic, dermatologic, or neurologic abnormality.

Evidence or history of anemia, thrombocytopenia, or leukopenia.

Use of any prescription or non-prescription drugs (excluding paracetamol), antacids, vitamins, herbal, and dietary supplements (including St John’s Wort) within 14 days (or 28 days if the drug is a potential hepatic enzyme inducer) or 5 half-lives (whichever is longer) prior to the first dose of study medication, unless in the opinion of the Investigator and Medical Monitor the medication will not interfere with the study procedures or compromise subject safety.

A positive pregnancy test (at Screening or on Day -1 of the (first) treatment period) or lactation.

A history or presence of any disease, condition, or surgery likely to affect drug absorption, distribution, metabolism, or excretion.

A clinically significant abnormality on physical examination, neurological examination, ECG, or laboratory evaluations at Screening or between Screening and (first) dose administration.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-03-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	01-03-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50828
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9309
CCMO	NL76587.056.21
OMON	NL-OMON50828

Study results