A First-in-Human Single Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetic and Exploratory Markers of Efficacy for XAB05 in Healthy Subjects.

Published: 30-11-2021
Last updated: 05-04-2024

Primary objective:• To evaluate the safety and tolerability of single intravenous (i.v.) doses of XAB05 in healthy subjects.Secondary objective:• To characterize the plasma pharmacokinetic (PK) profile of single i.v. doses of XAB05 in healthy...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON50582

Source
ToetsingOnline

Brief title
CS0377 Xenothera

Condition

- Bacterial infectious disorders

Synonym
treatment and the prevention of multidrug resistant (MDR) bacterial infections.

Research involving
Human

Sponsors and support

Primary sponsor: Xenothera SAS
Source(s) of monetary or material Support: Xenothera

Intervention

Keyword: First in human, Pharmacokinetic, Safety, Tolerability

Outcome measures

Primary outcome

• Safety and tolerability parameters include: physical examination, adverse

events (AEs), infusion site reactions/local tolerability, clinical laboratory

values, vital signs and electrocardiogram (ECG).

Secondary outcome

• PK parameters for XAB05 include: Cmax, tmax, Ceoi, t1/2, AUC0-t, AUC0-inf,

CL, Vz.

• Immunogenicity parameters include: anti-drug antibodies (ADA).

Study description

Background summary

Xenothera is developing a new generation of polyclonal hyperimmune purified immunoglobulins lacking immunogenic carbohydrate xenoantigens, called Glyco-humanized polyclonal antibodies (GH-pAbs), thereby avoiding the deleterious effects of classical polyclonals.
Product is named *XAB05* and is a polyclonal swine anti-bacterial glyco-humanized immunoglobulin preparation obtained by immunization of pigs knock out of two glycosylation genes with dPNAG, a variant of a common surface polysaccharide shared by a broad spectrum of pathogens. The targeted therapeutic indication of XAB05 is the treatment and the prevention of multidrug resistant (MDR) bacterial infections.
See the IB for full details.

Study objective

Primary objective:
• To evaluate the safety and tolerability of single intravenous (i.v.) doses of XAB05 in healthy subjects.
Secondary objective:
• To characterize the plasma pharmacokinetic (PK) profile of single i.v. doses of XAB05 in healthy subjects.
• To assess the immunogenicity of XAB05 after single i.v. doses of XAB05 in healthy subjects.

Study design

This is a randomized, placebo-controlled, first in human, single ascending dose study in healthy subjects.

Intervention

XAB05 or placebo

Study burden and risks

Since the study is being executed in healthy volunteers, there are no anticipated benefits of the IMP. Please see the IB for further information.

Contacts

Public
Xenothera SAS

1 rue Vauban 1
Nantes 44 000
FR
Scientific
Xenothera SAS

1 rue Vauban 1
Nantes 44 000
FR

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. The subject 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.
2. Healthy as determined by the Investigator, based on a medical evaluation including medical history, physical examination, laboratory tests and ECG recording. A subject with a clinical abnormality or laboratory parameters outside the reference range for the population being studied, may be included only if, in the opinion of the Investigator, the finding is (a) unlikely to introduce additional risk to the subject, (b) will not interfere with study procedures or confound study results, and (c) is not otherwise exclusionary (see Exclusion Criteria).
3. The subject is a male or female, aged 18 to 65 years, inclusive, at Screening.
4. The subject weighs at least 50 kg and has a BMI between 18.0 and 34.0 kg/m2, inclusive, at Screening and on Day -1.
5. Women of child-bearing potential must agree not to attempt to become pregnant and to use a highly effective form of hormonal (oral contraception, a hormonal implant, hormonal injection or hormonal intra-uterine devices) or non-hormonal (non-hormonal intra-uterine device/system in combination with a barrier method (e.g. condom, diaphragm, cervical cap with spermicide)) birth control or abstinence during the study and for 90 days after the (last) study drug administration. Postmenopausal women must have had >=12 months of spontaneous amenorrhea (with documented follicle-stimulating hormone (FSH) >=30 mIU/mL). Surgically sterile women are defined as those who have had a hysterectomy, bilateral ovariectomy, or bilateral tubal ligation. Women who are surgically sterile must provide documentation of the procedure by an operative report or by ultrasound. All women must have a negative pregnancy test result at Screening and on Day -1.

Exclusion criteria

1. The subject has history or evidence of clinically significant hematologic, dermatologic, neurologic, cardiovascular, pulmonary, hepatic, renal, metabolic, gastrointestinal, urologic including difficulty voiding, immunologic, endocrine disease, or psychiatric disorder, or other abnormality, which may impact the ability of the subject to participate or potentially confound the study results, or which, in the investigator*s opinion, makes subjects unsuitable for the study.
2. The subject has a significant history of allergies, as determined by the Principal Investigator.
3. The subject is taking antihistamines, NSAIDs, or mast cell stabilizers (e.g. disodium cromoglycate) and is unable to stop taking these medications from 7 days prior to Day 1.
4. The subject has received any prescription or non-prescription drugs (including steroids and COVID-19 vaccination, but excluding paracetamol, oral contraception, a hormonal implant or hormonal intra-uterine devices), vitamins and herbal remedies (including St John*s Wort), within 14 days or 5 half-lives (whichever is longer) prior to Day -1.
5. A clinically significant abnormality on physical examination, ECG, or laboratory evaluations at Screening or between Screening and study drug administration.
6. The subject has a supine blood pressure outside the ranges of 90 to 140 mm Hg for systolic and 45 to 90 mm Hg for diastolic, confirmed on repeat testing at Screening and on Day -1.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-01-2022
Enrollment:	35
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Nap.
Generic name:	Nap.

Ethics review

Approved WMO Date:	30-11-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-12-2021
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	EUCTR2021-005313-14-NL
CCMO	NL79831.056.21

Study results

Results posted: 25-09-2023

First publication
20-10-2022