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A study to determine the safety of higher doses of OMS906 in healthy volunteers

Submission date
22/02/2024

Recruitment status
No longer recruiting

Registration date
23/02/2024

Overall study status
Completed

Last Edited
15/12/2025

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The purpose of this study was to test a drug called OMS906 that is being developed for the treatment of inflammatory and autoimmune diseases, such as paroxysmal nocturnal haemoglobinuria (PNH). PNH is a rare blood condition where blood cells are attacked and destroyed by the immune system (the body's defence mechanism against infections and diseases). This was a study in healthy volunteers to investigate the safety of higher doses of OMS906. The other aims of the study were to see how the body absorbs and removes the study drug and to assess the effect of the study drug on the body.

Who can participate?
People who met certain criteria could participate, but in general, participants were male or female healthy volunteers aged between 18 and 60 years old, with a body mass index of between 18.0 and 30.0 kg/m2 and weight between 50 and 110 kg.

What does the study involve?
Participation in the study lasted approximately 29 weeks, with up to 13 visits to a Clinical Research Unit (including one 4 night stay). Participants either received a single dose of OMS906 or placebo (dummy drug) and had various tests including ECG, blood and urine tests.

What are the possible benefits and risks of participating?
There were no benefits to participating, apart from contribution to scientific knowledge which may lead to the expansion of treatment options for people with PNH. Risks from taking OMS906 included bacterial infections, temporary increases in heart rate, liver enzymes and white and red blood cell counts. There were also risks associated with drawing blood, taking ECGs and risks associated with vaccines for meningitis, which may have needed to be administered before the study start.

Where is the study run from?
MAC Clinical Research (UK)

When is the study starting and how long is it expected to run for?
The study started in March 2024 and ended in April 2025

Who is funding the study?
Omeros Corporation (USA)

Who is the main contact?
MAC Clinical Research

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
1008854

Protocol serial number
OMS906-NHV-004

Study information

Scientific Title
A Phase I study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of higher doses of OMS906 by single dose intravenous administration in healthy subjects

Acronym
OMS906-NHV-004

Study objectives
The primary objective of the study is to assess the safety and tolerability of single dose 8 mg/kg and 10 mg/kg or 12 mg/kg intravenous OMS906.

The secondary objectives of the study were:
1. To assess the pharmacokinetics of OMS906.
2. To assess the pharmacodynamics of OMS906.
3. To assess anti-drug antibodies (ADAs) following single dose 8 mg/kg and 10 mg/kg or 12 mg /kg IV OMS906.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 11/01/2024, Wales Research Ethics Committee 1 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2920 785738; Wales.REC1@wales.nhs.uk), ref: 23/WA/0330

2. Approved 12/01/2024, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0) 20 3080 6000;; info@mhra.gov.uk), ref: 49709/0006/001-0001

Primary study design
Interventional

Study design
Randomized double-blind single-centre placebo-controlled single-dose study in two sequential groups of healthy male and/or female subjects each

Study type(s)
Other

Health condition(s) or problem(s) studied
OMS906 is being developed to treat inflammatory and autoimmune diseases, such as paroxysmal nocturnal haemoglobinuria (PNH), a rare blood condition where blood cells are attacked and destroyed by the immune system

Interventions
OMS906 and placebo are administered by IV infusion over 30 minutes. Each subject receives a single dose of either OMS906 (8 mg/kg or 12 mg/kg) or placebo on Day 0 of the study and are followed up for approximately 140 days. A simple randomisation schedule has been produced using Statistical Analysis System Procedure (SAS PROC) PLAN and code break envelopes are available for the Investigator to open in an emergency.

Intervention Type
Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)
Zaltenibart (OMS906)

Primary outcome(s)
1. Safety and tolerability measured using Adverse Event monitoring at Day -1 to Day 140
2. Safety and tolerability measured using vital signs at Day -1, 0, 1, 2, 3, 4-6, 7, 28, 56, 84, 112, 140
3. Safety and tolerability measured using 12-lead ECGs at Day 0, 1, 2, 3, 4-6, 7, 28, 56, 84, 112, 140
4. Safety and tolerability measured using clinical laboratory tests at Day -1, 3, 7, 28, 56, 84, 112, 140

Key secondary outcome(s)
1. OMS906 pharmacokinetics (PK) measured using serum OMS906 concentrations for PK parameters at Day 0, 1, 2, 3, 4-6, 7, 28, 56, 84, 112, 140
2. OMS906 pharmacodynamics measured using change from baseline in MASP-3 and mature CFD in plasma at Day 0, 1, 2, 3, 4-6, 7, 28, 56, 84, 112, 140
3. Anti-Drug Antibodies (ADAs) measured using incidence of subjects with ADAs in serum at Day 0, 28, 56, 84, 112, 140

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. Healthy male or female aged ≥18 and ≤60 years at Screening.
2. Body mass index (BMI) ≥18.0 and ≤30.0 kg/m2 and total body weight ≥50 kg and ≤110 kg at Screening.
3. Non pregnancy of female participants confirmed. Male and female contraceptive requirements.
4. Cessation of all prescribed medications (excluding the contraceptive pill) at least 14 days prior to admission to the Clinical Research Unit (CRU).
5. Cessation of all over the counter medications, vitamin preparations and other food supplements or herbal medications at least 7 days prior to admission to the CRU (except paracetamol/acetaminophen, which was permitted up to admission to the CRU).
6. Ability and willingness to abstain from alcohol use for the 48 hours prior to admission to the CRU and throughout confinement.
7. Good physical and mental health based on medical history, physical examination, clinical laboratory, ECG, and vital signs, as judged by the Investigator.
8. Mandatory documentation of prior N. meningitidis vaccination (MenABCWY), otherwise participant was to start vaccinations or receive boosters during Run-In.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group

Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
16

Key exclusion criteria
1. Receipt of a complement inhibitor within 6 months of Screening.
2. History of any significant allergic, medical, haematologic, neurologic, or psychiatric disorder or social reason that in the opinion of the Investigator would have made the subject unsuitable for participation in the study.
3. Subjects with values greater than the upper limit of normal (ULN) for the following laboratory tests: creatinine, creatine phosphokinase (CPK), LDH, alkaline phosphatase (ALP), aspartate aminotransferase (AST), alanine aminotransferase (ALT), total bilirubin and direct bilirubin that remained elevated on repeat sampling and analysis
4. Significant active bacterial or viral infection or acute illness within 2 weeks prior to Screening including coronavirus disease 2019 (COVID-19) infection.
5. Positive screen for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen on nasal swab, or the hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV) antibodies, or human immunodeficiency virus (HIV) 1 and 2 antibodies in blood.
6. Plasma or platelet donation within 14 days prior to Day 0.
7. History of asplenia, hyposplenism, or splenectomy.
8. History of significant autoimmune disease.

Date of first enrolment
06/03/2024

Date of final enrolment
10/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MAC Clinical Research Manchester
Citylabs 1.0
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M13 9NQ

Sponsor information

Organisation
Omeros Corporation (United States)

ROR
https://ror.org/01r5k6556

Funder(s)

Funder type
Industry

Funder Name
Omeros Corporation

Alternative Name(s)
Omeros, Omeros Corp, OMS

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Basic results	15/12/2025	15/12/2025	No	No