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OM336 in seropositive autoimmune diseases

Submission date
09/10/2025

Recruitment status
Recruiting

Registration date
22/10/2025

Overall study status
Ongoing

Last Edited
15/10/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a Phase 1b clinical study testing an investigational medicine called OM336 in adults with either Sjögren's disease (SjD) or idiopathic inflammatory myopathy (IIM). These are autoimmune diseases where the body's immune system attacks its own tissues, causing long-term inflammation, pain, and fatigue.

The purpose of this study is to find out whether OM336 is safe and well-tolerated when given to people with active SjD or IIM. The study will also help researchers understand how the body responds to OM336 and whether it improves disease symptoms.

Who can participate?
Patients with a diagnosis of active seropositive autoimmune disease between 18 and 75 years of age.

What does the study involve?
Everyone enrolled will receive the study drug—there is no placebo group. Participants will be closely monitored through medical exams, blood and urine tests, and regular check-ups over approximately a year.

What are the possible benefits and risks of participating?
OM336 is still an experimental drug, so its benefits and risks are not fully known. Early research suggests it may help control the overactive immune system and reduce the need for other medications such as steroids. The most common risks relate to immune suppression and possible infection. Doctors will monitor participants carefully and may prescribe antibiotics or other medicines if needed.

Where is the study run from?
Ouro Medicines Ltd.

When is the study starting and how long is it expected to run for?
August 2025 to March 2028

Who is funding the study?
Ouro Medicines Ltd.

Who is the main contact?
clinical@ouromeds.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
2025-524100-29-00

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
OM336-SAI-1002

Study information

Scientific Title
An open-label, phase 1b, multiple ascending dose study of OM336 in participants with active Sjogren’s disease or idiopathic inflammatory myopathy

Study objectives
An early-phase clinical trial evaluating the safety, tolerability, and pharmacokinetics of OM336 in adult participants with seropositive autoimmune diseases.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 22/09/2025, Northern A Health and Disability Ethics Committee (HDEC) (New Zealand Ministry of Health, PO Box 5013, Wellington, 6140, New Zealand; -; hdecs@health.govt.nz), ref: 2025 FULL 23606

2. submitted 06/08/2025, Department of Health WA Human Research Ethics Committee (DoH HREC) (PO Box 8172, Perth Business Centre, Perth, 9849, Australia; +61 8 9222 4214; hrec@health.wa.gov.au), ref: 2025-09-1433

Study design
Open-label multicenter multiple-ascending-dose study

Primary study design
Interventional

Study type(s)
Treatment, Safety

Health condition(s) or problem(s) studied
Sjogren's Disease (SjD), Idiopathic Inflammatory Myopathy (IIM)

Interventions
Generic drug name / active substance:
OM336 (INN pending; recombinant humanized bispecific antibody directed at BCMA and CD3).

Treatment Arms
OM336 is administered in 3 multiple ascending dose (MAD) cohorts and 3 expansion cohorts as summarized below:

Cohorts / Treatment Arms:
• Cohort A1: 5 participants (lowest dose)
• Cohort A2: 5 participants (intermediate dose)
• Cohort A3: 5 participants (highest dose)
• Cohorts B1–B3: Expansion cohorts (up to 8 participants each) at the corresponding dose levels of A1–A3 once safety and tolerability at that dose level are confirmed.

Dose and administration:
OM336 is administered once weekly by subcutaneous (SC) injection as four fractionated, step-up injections.

Dosing regimen:
• Week 1 (Day 1): lowest dose
• Week 2 (Day 8 ± 2 days): intermediate dose
• Week 3 (Day 15 ± 2 days): target dose
• Week 4 (Day 22 ± 2 days): repeat target dose
Dose levels differ by cohort and are determined from prior safety data. All participants receive active drug.

Post-treatment care / concomitant prophylaxis:
Investigators may prescribe antibiotic or antiviral prophylaxis according to local guidelines. Intravenous immunoglobulin (IVIg) replacement may be given.

Follow-up period:
Participants are followed for approximately 52 weeks after the first dose, with regular site visits for clinical exams, laboratory monitoring, and pharmacokinetic/immunogenicity sampling.

Randomization and blinding:
None — this is an open-label, non-randomized study; all participants receive active OM336.

Duration of entire intervention period:
Up to four weeks of screening + four weeks of dosing + 48 weeks of safety follow-up = total ~56 weeks per participant.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
OM336

Primary outcome(s)
Safety and tolerability, defined as the incidence and severity of treatment-emergent adverse events (TEAEs) measured through participant reports, clinical assessments, and laboratory tests, and graded for severity using CTCAE at 12 weeks

Key secondary outcome(s))
1. Safety and tolerability, defined as the incidence and severity of treatment-emergent adverse events (TEAEs), measured through participant reports, clinical assessments, and laboratory tests, and graded for severity using CTCAE at 52 weeks
2. To assess the pharmacokinetics (PK) of OM336 measured from scheduled patient samples analyzed using validated bioanalytical assays at 12 weeks
3. Detection of anti-drug antibodies measured from scheduled patient samples analyzed using validated bioanalytical assays at 12 weeks

Completion date
01/03/2028

Eligibility

Key inclusion criteria
1. Diagnosis of active seropositive autoimmune disease
2. Relapsed/refractory after ≥2 prior/ongoing treatments
3. Body weight ≥ 50 kg
4. Willing to comply with and study requirements and procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Previous treatment with a BCMA-targeted therapy
2. Clinically significant infection within 3 months of screening
3. Major surgery within 3 months of screening or planned during the study
4. Pregnant or breastfeeding

Date of first enrolment
30/11/2025

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
Australia

New Zealand

Study participating centre
Waikato Hospital
Hamilton
New Zealand
3204

Study participating centre
The Canberra Hospital
Garran
Australia
2605

Sponsor information

Organisation

Ouro Medicines Ltd.

Funder(s)

Funder type
Industry

Funder Name
Ouro Medicines, Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes