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A phase 1/1b study to evaluate safety, tolerability and pharmacokinetics of ZL-1503 in healthy volunteers and participants with moderate to severe atopic dermatitis

Submission date
03/11/2025

Recruitment status
No longer recruiting

Registration date
04/11/2025

Overall study status
Ongoing

Last Edited
03/11/2025

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
This is a phase 1/1b randomized, double blind, placebo-controlled, single dose escalation (SAD) and multiple dose escalation (MAD) study to evaluate the safety, tolerability, and pharmacokinetics (PK) of ZL-1503 in healthy volunteers and participants with moderate to severe atopic dermatitis (AD)

Who can participate?
SAD: Healthy male and non-pregnant, non-lactating female participants, 18-65 years of age, inclusive
MAD: Male and non-pregnant, non-lactating female participants with moderate to severe atopic dermatitis (AD), 18-65 years of age, inclusive

What does the study involve?
Participants are randomly assigned to receive either ZL-1503 or a placebo as a single dose or multiple doses to determine the safety and the way people process the drug. The total maximum study duration for participants is about 1 year.

What are the possible benefits and risks of participating?
No clinical benefit is anticipated for healthy volunteers. However, participants may benefit society by contributing to the process of developing new therapies in an area of unmet need. Additionally, participants will benefit from medical evaluations/assessments associated with study procedures (e.g., physical examination, electrocardiogram [ECG], labs, etc.).

Where is the study run from?
Zai Lab (Shanghai) Co., Ltd (China)

When is the study starting and how long is it expected to run for?
September 2025 to December 2027

Who is funding the study?
Zai Lab (Shanghai) Co., Ltd (China)

Who is the main contact?
ZaiLab_1503-001_StudyTeam@zailaboratory.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
ZL-1503-001

Study information

Scientific Title
A phase 1/1b randomized, double blind, placebo-controlled, single and multiple dose escalation study to evaluate the safety, tolerability, and pharmacokinetics of ZL-1503 in healthy volunteers and participants with moderate to severe atopic dermatitis (AD)

Study objectives
The main objective of this study is to evaluate the safety and tolerability of ZL-1503. The secondary objectives are to evaluate the pharmacokinetics (PK) and immunogenicity of ZL-1503. The data obtained from this FIH study will inform dose selection for subsequent clinical development and will help with the design of future studies.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 11/09/2025, Health and Disability Ethics Committee (133 Molesworth Street, Wellington, 6140, New Zealand; -; hdecs@health.govt.nz), ref: 2025FULL23878

Primary study design
Interventional

Study design
Multicenter interventional phase 1/1b randomized double blind placebo-controlled single and multiple dose escalation study

Study type(s)
Safety

Health condition(s) or problem(s) studied
Safety and tolerability in healthy volunteers and participants with moderate to severe atopic dermatitis

Interventions
Healthy volunteers in the SAD part of the study will enrol sequentially into 4 single dose cohorts from New Zealand. Two additional cohorts of Chinese healthy volunteers will enrol sequentially in China. Within each cohort, participants will be randomized to receive a single IV dose of ZL-1503 or placebo.

In the MAD part of the study, participants with moderate to severe atopic dermatitis will enrol sequentially into 2 multiple dose cohorts. Within each cohort, participants will be randomized to receive multiple IV doses of ZL-1503 or placebo.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
ZL-1503

Primary outcome(s)
Safety and tolerability of ZL-1503 assessed using incidence of Adverse Events (AEs) and serious adverse events (SAEs) coded based on the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE). Incidence of clinically significant laboratory findings (Chemistry, Hematology. Urinalysis). Incidence of clinically significant vital signs include pulse rate measured via brachial/radial artery, blood pressure through digital Sphygmomanometer, body temperature, and respiratory rate. Incidence of clinically significant changes in electrocardiograms.
Timepoints:
Part A (SAD): Adverse events, clinical laboratory and blood and urine samples, vital signs and ECGs from screening up to Day 337.
Part B (MAD): Adverse events, clinical laboratory and blood and urine samples, vital signs and ECGs from screening up to Day 365.

Key secondary outcome(s)
1. PK parameters of ZL-1503 may include, but are not limited to, maximum serum concentration (Cmax), time to reach maximum concentration (Tmax), area under the concentration-time profile (AUC), half-life (t1/2), volume of distribution at steady-state (Vss), clearance (CL) and accumulation ratio, as applicable.

Timepoint:
Part A (SAD): PK samples will be collected from pre-dose on Day 1 up to Day 337.
Part B (MAD): PK samples will be collected from pre-dose on Day 1 up to Day 365.

2. ZL-1503 Immunogenicity measured using the incidence of anti-drug antibody (ADA).
Timepoint:
Part A (SAD): ADA samples will be collected from pre-dose on Day 1 up to Day 337.
Part B (MAD): ADA samples will be collected from pre-dose on Day 1 up to Day 365.

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Part A (SAD):
A1. Healthy male and female volunteers, 18-65 years of age
A2. Body mass index (BMI) between ≥ 18.5 and < 32.5 kg/m²
A3. Negative pregnancy tests for women of childbearing potential

Part B (MAD):
B1. 18-65 years of age
B2. BMI between ≥18.5 and <40.0 kg/m²
B3. Have a diagnosis of AD at least 12 months prior to Day 1
B4. Moderate-to-severe AD at Screening and Baseline visit, defined as:
B4.1. Eczema Area and Severity Index (EASI) score ≥ 1
B4.2. Affected Body Surface Area (BSA)≥ 10%
B4.3. vIGA-ADTM score ≥ 3
B5. History of an inadequate response to treatment with topical medications
B6. Average peak pruritus numeric rating scale (PP-NRS) score ≥4 in the 7 days before randomization
B7. Negative pregnancy tests for women of childbearing potential

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
Part A and B:
1. Significant health issues, such as positive tests for human immunodeficiency virus (HIV), hepatitis C virus (HCV), hepatitis B virus (HBV), active tuberculosis, immunodeficiencies or autoimmune diseases.
2. History of major metabolic, liver, kidney, hematologic or other significant disorders.
3. Abnormal Electrocardiogram (ECG) findings
4. Clinically relevant abnormal lab results, including low blood counts, or abnormal liver and kidney function.
5. History of drug abuse or addiction within 6 months prior to screening
6. Current smoker or use of any nicotine or tobacco containing products within the last 6 months prior to dosing.
7. Donated >500mL blood within 2 months of dosing.

Part B only:
B8. Presence of dermatologic conditions and/or comorbidities that might confound the diagnosis of AD and/or might interfere with study assessments.
B9. Uncontrolled chronic disease that might require bursts of oral corticosteroids.
B10. Any other sound medical, psychiatric, and/or social reason as determined by the investigator.

Date of first enrolment
04/12/2025

Date of final enrolment
20/11/2026

Locations

Countries of recruitment
China

New Zealand

Study participating centre
Pacific Clinical Research Network
2/2 Fred Thomas Drive
Auckland
New Zealand
6022

Sponsor information

Organisation
Zai Lab (Shanghai) Co., Ltd

Funder(s)

Funder type
Industry

Funder Name
Zai Lab (Shanghai) Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan
Individual results from the clinical trial will not be made available to study participants or others.

IPD sharing plan summary
Not expected to be made available