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A study to test the safety and effects of a New Drug (LAE103) in healthy people who are overweight or obese, and in healthy postmenopausal women. The study also looks at how LAE103 works when taken alone or together with another drug (LAE102).

Submission date
04/11/2025

Recruitment status
Recruiting

Registration date
05/11/2025

Overall study status
Ongoing

Last Edited
24/02/2026

Condition category
Nutritional, Metabolic, Endocrine

[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
LAE103 is a highly specific, fully human monoclonal antibody (mAb) targeting human ACVR2B, and LAE102 is a highly specific mAb targeting human ACVR2A. As an antagonist, LAE103 completely blocks the interaction between ACVR2B and its ligands, including activins such as Activin A, Activin B, Activin AB, Activin C, Activin AC, Activin E, and growth differentiation factors (GDFs) such as GDF8 (myostatin) and GDF11. Similarly, LAE102 could completely block the interaction between these ligands and the receptor ACVR2A.

Who can participate?
Healthy adult volunteers

What does the study involve?
This study will enroll approximately 104 participants, in 4 parts:
Part A is a single ascending (increasing) dose (SAD) study, where approximately 40 participants will receive a single dose of the study drug or placebo.
Part B is a single ascending (increasing) dose (SAD) study, where approximately 16 post-menopausal women will receive a single dose of the study drug or placebo.
Part C is a multiple ascending (increasing) dose (MAD) study, where approximately 24 participants will receive 5 doses of the study drug or placebo.
Part D is a single ascending (increasing) dose (SAD) study, which will investigate the effects of LAE103 and LAE102 when given together.

Approximately 24 participants will receive the study drug or placebo.
For Parts A, B and D: The study will involve a 4-week screening period, a 7-night inpatient stay,

and 6 follow-up visits. The total duration of the study participation is 14 weeks, including screening.
For Part C: The study will involve a 4-week screening period, a 9-night inpatient stay, followed by two 2-night stays and a final 7-night stay, and 6 follow-up visits. The total duration of the study participation is 18 weeks, including screening.

What are the possible benefits and risks of participating?
There is no direct benefit to participants. This study may help develop important scientific knowledge that could contribute to the development of a potential new treatment for people who are overweight and obese. LAE103 is a new study drug; therefore, the risks to human participants are not fully known. There could be side effects that are not expected or are not known.

Where is the study run from?
Laekna Limited, China

When is the study starting and how long is it expected to run for?
September 2025 to December 2026. The first participant is expected to be enrolled in Part A cohort 1 in November 2025. The last participant is expected to be enrolled in Part C cohort 10 in December 2026.

Who is funding the study?
Laekna Limited, China

Who is the main contact?
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Additional identifiers

Protocol serial number
LAE103INT1001

Study information

Scientific Title
A phase I, randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of LAE103 as single and multiple ascending doses in healthy overweight/obese participants, and as single dose in healthy postmenopausal women, with an additional evaluation of single ascending dose of LAE103 in combination with LAE102 in healthy overweight/obese participants

Study objectives
The main objective of this study is to evaluate the safety and tolerability of LAE103 and LAE103 in combination with LAE102.
The secondary objectives are to evaluate the pharmacokinetics (PK), change in serum Activin A levels, and immunogenicity of LAE103 or LAE103 given in combination with LAE102. For Part B, secondary objectives also include effect on FSH levels after dosing with LAE103.

There is no formal hypothesis for this study.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/10/2025, Bellberry Human Research Ethics Committee (HREC) (123 Glen Osmond Road, Eastwood, SA 5063, Australia; +61 8 8361 3222; bellberry@bellberry.com.au), ref: 2025-10-1672

Study design
Single center interventional double-blinded randomized placebo-controlled trial

Primary study design
Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied
Safety and tolerability in healthy overweight/obese volunteers

Interventions
Study treatment:
Investigational product 1: LAE103
Investigational product 2: LAE102
Placebo: Sodium Chloride

Part A: Healthy overweight/obese volunteers will be randomised sequentially into five single dose cohorts, with planned LAE103 doses of 0.7 mg/kg (Cohort 1), 2 mg/kg (Cohort 2), 4 mg/kg (Cohort 3), 8mg/kg (cohort 4) and 12 mg/kg (Cohort 5), respectively. 8 participants per cohort - 6 treated with LAE103, 2 participants treated with placebo.
Part B: Healthy post-menopausal female volunteers will be randomised sequentially into two single-dose cohorts, with planned LAE103 doses of 4 mg/kg (Cohort 6) and 8mg/kg (Cohort 7), respectively. 8 participants per cohort - 6 treated with LAE103, 2 participants treated with placebo.
Part C: Healthy overweight/obese volunteers will be randomised sequentially into three multiple dose cohorts, with planned doses of 2 mg/kg QW for a total of five doses (Cohort 8), 4 mg/kg QW for a total of five doses (Cohort 9) and 8 mg/kg QW for a total of five doses (Cohort 10), respectively. 8 participants per cohort - 6 treated with LAE103, 2 participants treated with placebo.
Part D: Healthy overweight/obese volunteers will be randomised sequentially into three single dose cohorts, with planned doses of 0.7 mg/kg LAE103 + 4mg/kg LAE102 (Cohort 11), 2 mg/kg LAE103 + 4mg/kg LAE102 (Cohort 12) and 4 mg/kg LAE103 + 4mg/kg LAE102 (Cohort 13), respectively. 8 participants per cohort - 6 treated with LAE103, 2 participants treated with placebo.

Participants in cohorts of Part A, B, C and D will be randomised through a randomization schedule generated using the statistics analysis system (SAS) PROC PLAN by the independent statistician and provided to the site in sealed envelopes, one for each randomisation number.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
LAE103, Combination LAE103 + LAE102

Primary outcome(s)
1. Part A: Evaluate the safety and tolerability of LAE103 in healthy overweight/obese participants following a single SC injection. Measured through incidence of TEAEs, vital signs, physical examinations, 12-lead ECG, and clinical laboratory tests within 70 days of dose administration.
2. Part B: Evaluate the safety and tolerability of LAE103 in post-menopausal female participants following a single SC injection. Measured through incidence of TEAEs, vital signs, physical examinations, 12-lead ECG, and clinical laboratory tests within 70 days of dose administration.
3. Part C: Evaluate the safety and tolerability of LAE103 in healthy overweight/obese participants following multiple SC injections. Measured through incidence of TEAEs, vital signs, physical examinations, 12-lead ECG, and clinical laboratory tests within 98 days of first dose administration.
4. Part D: Evaluate the safety and tolerability of LAE103 given in combination with LAE102 in

healthy overweight/obese participants following a single SC injection. Measured through incidence of TEAEs, vital signs, physical examinations, 12-lead ECG, and clinical laboratory tests within 70 days of dose administration.

Key secondary outcome(s))

1. Part A-1: Evaluate the PK profile of LAE103 in healthy overweight/obese participants following a single SC injection. Measured through serum concentrations versus time and PK parameters (Cmax, Tmax, AUC0-t, AUC0-∞, t1/2, CL/F (s.c.) , Vz/F (s.c.), etc.) of LAE103 from pre-dose to 70 days post dose.
2. Part A-2: Evaluate the change in serum Activin A levels in healthy overweight/obese participants following a single SC injection of LAE103. Measured through change and percentage change from baseline in serum Activin A levels from pre-dose to 70 days post dose.
3. Part A-3: Evaluate the immunogenicity of LAE103 in healthy overweight/obese participants following a single SC injection. Measured through incidence and titers of positive ADA after administration from pre-dose to 70 days post dose.
4. Part B-1: Evaluate the PK profile of LAE103 in post-menopausal female participants following a single SC injection. Measured through serum concentrations versus time and PK parameters (Cmax, Tmax, AUC0-t, AUC0-∞, t1/2, CL/F (s.c.) , Vz/F (s.c.), etc.) of LAE103 from pre-dose to 70 days post dose.
5. Part B-2: Evaluate the change in serum Activin A levels in post-menopausal female participants following a single SC injection of LAE103. Measured through change and percentage change from baseline in serum Activin A levels from pre-dose to 70 days post dose.
6. Part B-3: Evaluate the immunogenicity of LAE103 in post-menopausal female participants following a single SC injection. Measured through incidence and titers of positive ADA after administration from pre-dose to 70 days post dose.
7. Part B-4: Evaluate the effect of LAE103 on FSH levels in healthy postmenopausal women following a single SC injection. Measured through change and percentage change from baseline in FSH levels from pre-dose to 70 days post dose.
8. Part C-1: Evaluate the PK profile of LAE103 in healthy overweight/obese participants following multiple SC injections. Measured through serum concentrations versus time and PK parameters (Cmax, Tmax, AUC0-t, AUC0-∞, t1/2, CL/F (s.c.) , Vz/F (s.c.), etc.) of LAE103 from pre-dose to 98 days post initial dose.
9. Part C-2: Evaluate the change in serum Activin A levels in healthy overweight/obese participants following multiple SC injections of LAE103. Measured through change and percentage change from baseline in serum Activin A levels from pre-dose to 98 days post dose.
10. Part C-3: Evaluate the immunogenicity of LAE103 in healthy overweight/obese participants following multiple SC injections of LAE103. Measured through incidence and titers of positive ADA after administration from pre-dose to 70 days post dose.
11. Part D-1: Evaluate the PK profile of LAE103 and LAE102 in healthy overweight/obese participants following a single SC injection. Measured through serum concentrations versus time and PK parameters (Cmax, Tmax, AUC0-t, AUC0-∞, t1/2, CL/F (s.c.) , Vz/F (s.c.), etc.) of LAE103 from pre-dose to 70 days post dose.
12. Part D-2: Evaluate the change in serum Activin A levels in healthy overweight/obese participants following a single SC injection of LAE103 in combination with LAE102. Measured through change and percentage change from baseline in serum Activin A levels from pre-dose to 70 days post dose.
13. Part D-3: Evaluate the immunogenicity of LAE103 and LAE102 in healthy overweight/obese participants following a single SC injection of LAE103 given in combination with LAE102. Measured through incidence and titers of positive ADA after administration from pre-dose to 70 days post dose.

Completion date
30/12/2026

Eligibility

Key inclusion criteria
1. Informed consent: Are capable of giving signed informed consent and comply with the requirements and restrictions listed in the ICF and in this protocol.
2. Age at the time of signing the ICF:
2.1. Parts A, C, and D: Male or female participants aged 18 to 55 years, inclusive. Each cohort must include at least 3 female and 3 male participants.
2.2. Part B: Female participants aged 45 to 75 years, inclusive.
3. BMI at screening:
3.1. Parts A, C, and D: Have a BMI within the range of 25.0 to 40.0 kg/m2 (inclusive).
3.2. Part B: Have a BMI within the range of 20.0 to 35.0 kg/m2 (inclusive).
4. For female participants:
4.1. Participants without childbearing potential: defined as either postmenopausal or surgically sterile: including surgical sterilization; postmenopausal women defined as an individual who has had at least 12 months of spontaneous amenorrhea without an alternative medical cause and a FSH level in the postmenopausal range (≥ 40 IU/L at screening), or
4.2. Participants with childbearing potential, non-pregnant, non-lactating, must agree to use two forms of effective methods of contraception (at least one form must be highly effective) for the duration of the study, and 13 weeks after the last investigational product administration. During this period, participants should not donate eggs. Serum hCG test must < 5 mIU/mL at both the screening visit and D-1. Hormonal contraceptives should be commenced one month prior to screening to ensure contraceptive is in full effect. Complete abstinence is acceptable if it is part of the participant's usual and preferred lifestyle. Participants who are in same-sex relationships and continuously not heterosexually active are exempt from contraceptive requirements. However, WOCBP must still undergo pregnancy testing as per protocol (This would only apply to Parts A, C, and D, details of contraception guidance refer to 12.3).
5. Male participants with female partners of childbearing potential must agree to use adequate methods of contraception, which is defined as use of a condom by the male partner combined with use of a highly effective method of contraception by the female partner for the duration of the study and for 22 weeks after the last dosing. Male participants are not allowed to donate sperm for the same period. Hormonal contraceptives used by the female partner should have commenced one month prior to screening to ensure contraceptive is in full effect.
6. Type of participant and disease characteristics
6.1. Are overtly healthy participants, as determined by medical evaluation including medical history, physical examination, laboratory tests, and ECG.
6.2. Have FSH levels ≥ 40 IU/L at screening (Part B only).
6.3. Have liver function tests and all other clinical laboratory tests results within the normal range for the population, or results deemed not clinically significant at the discretion of the investigator.
6.4. Have venous access sufficient to allow for blood sampling as per the protocol or have no anticipated contraindications to receiving investigational products via SC delivery.
7. Are willing to make themselves available for study visits for the duration of the study and are willing to follow study procedures.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Have a history or presence of clinically significant medical condition(s), including, but not limited to, any
1.1. Cardiovascular, cerebrovascular, gastrointestinal (including hepatic) diseases.
1.2. Diabetes, or glycated hemoglobin (HbA1c) ≥6.5% or fasting blood glucose ≥7.0 mmol/l, medullary thyroid carcinoma, type 2 multiple endocrine neoplasia, chronic pancreatitis, and thyroid disorders.
1.3. Conditions affecting skin, respiratory, cardiovascular, digestive, renal, blood, endocrine, and reproductive systems.
1.4. Diagnosed with secondary overweight or obesity, such as obesity caused by metabolic diseases (such as Cushing's syndrome, hypothyroidism, etc.) or drug-induced obesity (such as glucocorticoids, tricyclic antidepressants, atypical antipsychotic drugs, etc.).
1.5. Psychiatric or neurological disease.
1.6. Neuromuscular disorder, including, but not limited to, multiple sclerosis, myasthenia gravis, myopathy, peripheral neuropathy, muscular dystrophy, or amyotrophic lateral sclerosis.
1.7. Inflammatory or autoimmune diseases that may cause muscle wasting, including, but not limited to, systemic lupus erythematosus (SLE) or rheumatoid arthritis (RA).
1.8. Inflammatory myopathies, including but not limited to polymyositis or dermatomyositis.
1.9. Other disease, abnormality or physiological conditions that would pose an unacceptable risk to study participants or confound the interpretation of the data collected during the study.
1.10 Individuals who have had a diagnosis of acute pancreatitis.
1.11 Individuals who have self-perceived dullness or loss of sensation on either side of their abdomen, or have, in the investigator’s opinion, excessive tattoos or scars over the arm, thigh, abdomen or other factors (for example, rash, excessive fold of skin) that would interfere with injection-site assessments.
2. Have a history of any malignancy within the past 5 years other than
2.1. Basal cell or squamous epithelial carcinomas in situ,
2.2. Cervical carcinoma in situ that has been resected with no evidence of metastatic disease for 3 years.
3. Have a fasting serum triglyceride level of more than 500 mg/dL(5.6 mmol/L) at screening.
4. Have an estimated glomerular filtration rate (eGFR) calculated by the Chronic Kidney Disease-Epidemiology (CKD-EPI) creatinine 2021 equation
4.1. Less than 90 mL/min/1.73 m2 at screening for Part A, C, and Part D

4.2. Less than 60 mL/min/1.73 m2 at screening for Part B.
5. Have
5.1. An abnormality in the 12-lead ECG that, in the opinion of the investigator, increases the risks associated with participating in the study, or
5.2. Confirmed supine Fridericia's corrected QT (QTcF) interval greater than 450 msec at screening.
6. Have an abnormal blood pressure defined as:
6.1. Diastolic blood pressure greater than 90 mmHg, or less than 60 mmHg
6.2. Systolic blood pressure greater than 140 mmHg, or less than 90 mmHg
7. Show evidence at screening of:
7.1. Human immunodeficiency virus (HIV) or positive human HIV antibodies
7.2. Hepatitis C or positive hepatitis C antibodies
7.3. Hepatitis B or positive hepatitis B surface antigen.
8. Have
8.1. A history of, or known hypersensitivity to study intervention or its excipients, or
8.2. A history of, or known hypersensitivity to monoclonal antibody drugs, or
8.3. A history of any severe allergies (including any food or drug allergies).
9. Underwent major surgery within 30 days prior to study intervention administration or plan to undergo major surgery during the study.
10. Self-reported weight change is more than 5% in the previous 3 months prior to screening.
11. Engaged in regular weightlifting, fitness, or strength training aimed at enhancing muscle strength.
12. Use of GLP-1 receptor agonists, or weight loss medications such as orlistat, naltrexone /bupropion, or systemic corticosteroids (oral or intravenous for more than 7 days), or psychiatric medications (e.g., tricyclic antidepressants, olanzapine) within 3 months prior to the first dose of the investigational product.
13. Have used in the past 90 days (before screening) or intend to use during the study any medication that may affect FSH levels, including but not limited to:
13.1. Hormonal replacement therapy
13.2. Systemic corticosteroid therapy longer than 2 weeks, or
13.3. Growth hormone therapies.
14. Have used or intend to use prescription or over-the-counter medications, or herbal medicines, for 14 days or 5 half-lives (if known), whichever is longer, prior to study intervention administration until the last visit.
15. Received any vaccine 30 days prior to screening or plan to receive any vaccine during the study.
16. Have participated, are currently enrolled in, or discontinued from a clinical trial involving an investigational drug or device or off-label use of a drug or device within the last 90 days, or 5-half-lives (if known, whichever is longer), of the last administration of study drug or application of the device, or any other type of medical research judged not to be scientifically or medically compatible with this study.
17. Have previously completed or withdrawn from this study or any other study investigating this study intervention.
18. Have
18.1. An average weekly alcohol consumption exceeding 14 units per week for female participants, 21 units per week for male participants, or
18.2. Positive alcohol test at screening or admission, or
18.3. A history of alcohol abuse disorder within 1 year prior to screening, or
18.4. An inability or unwillingness to stop alcohol consumption 7 days prior to dosing.
19. Have
19.1 known or suspected history of substance abuse (such as morphine, methamphetamine, ketamine, methylenedioxyamphetamine, tetrahydrocannabinol), or

19.2. test positive for drugs of abuse at screening or admission.
20. Are
20.1. Smoking more than 5 cigarettes (or the equivalent of other tobacco products) per day within 90 days prior to screening, or
20.2. Unable or unwilling to stop smoking tobacco products during the confinement period.
21. Have donated blood or experienced blood loss of more than 400 mL within 30 days prior to screening.
22. Are
22.1. Fasting or receiving weight loss treatment within 30 days prior to study intervention administration, or
22.2 Experiencing major changes in lifestyle (e.g., abrupt initiation of a dietary regimen or an augmenting physical activity aiming to lose weight).
23. In the opinion of the investigator or Sponsor and medical monitor, they are unsuitable for inclusion in the study.
24. Are Laekna Limited. employees, CRO employees, investigator, or site personnel directly affiliated with this study or the immediate families of any of these. Immediate family is defined as a spouse, parent, child, or sibling, whether biological or legally adopted.
25. Have contraindications for an MRI scan or do not meet the requirements for an MRI scan as per local guidelines. (This criterion applies only to Parts C and D.)

Date of first enrolment
30/12/2025

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
Australia

Study participating centre
Q-Pharm Pty Limited
Level 5, Clive Berghofer Cancer Research Centre, 300c Herston Road
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Sponsor information

Organisation
Laekna Limited

Funder(s)

Funder type
Industry

Funder Name
Laekna Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available