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A study testing the safety and effects of FB-102 in healthy volunteers

Submission date 18/05/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/05/2026	**Overall study status** Ongoing	
Last Edited 28/05/2026	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

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Study information

Scientific Title
A phase 1, randomized, double-blind, placebo-controlled trial to evaluate the safety and effects after single and multiple dose administration of FB-102

Study objectives
The purpose of this Phase 1 trial is to evaluate the safety and effects of FB-102 in healthy volunteers following single and multiple doses.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 25/05/2026, Bellberry Human Research Ethics Committee A (Level 1, 196 Greenhill Road Eastwood Adelaide South Australia 5063, Eastwood, 5063, Australia; 0883613222; bellberry@bellberry.com.au), ref: 2026-04-572

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Sequential

Purpose
Basic science

Study type(s)

Health condition(s) or problem(s) studied
Healthy volunteer

Interventions
Intervention Description
Experimental interventions consist of FB-102 administered as either a single dose or multiple doses, compared with a placebo control.

FB-102 (Investigation Product, IP)
Part A (single ascending dose, SAD), participants will receive a single subcutaneous or IV dose of FB-102. Participants will be randomized in a 3:1 ratio of FB-102 or placebo.

Part B (multiple ascending dose, MAD), participants will receive multiple subcutaneous doses of FB-102. Participants will be randomized in a 3:1 ratio of FB-102 or placebo.

Placebo comparator:
The placebo will be administered on the same schedule as the corresponding FB-102 cohort in accordance with the 3:1 randomization schema.

The randomization code will be generated by our statistician, and randomization will occur manually at the site by an unblinded pharmacist who will not otherwise be involved in the study.

Intervention Type
Biological/Vaccine

Phase
Phase I

Drug/device/biological/vaccine name(s)
FB-102

Primary outcome(s)
1. Incidence, severity, and relationship to treatment of treatment-emergent adverse events (TEAEs) measured using data collected from electronic Case Report Forms (eCFR) from day 1 to day 85 (end of treatment visit) at one time point

Key secondary outcome(s))

Completion date
17/02/2027

Eligibility

Key inclusion criteria
1. Body mass index (BMI) between 18.0 and 32.0kg/m2, inclusive, at Screening
2. Weight ≥50 kg and ≤100kg
3. Men are required to agree to practice true abstinence; be surgically sterilized (performed at least 6 months prior and documented to no longer produce sperm - verbal confirmation through medical history review acceptable); or agree to use a condom plus effective contraception for their female partner if of childbearing potential, from Screening and for at least 90 days after the EOT visit and refrain from donating sperm during this period. Effective contraception includes established use of hormonal contraception beginning at least
4. Women are eligible to participate if they are not pregnant, not breastfeeding, and at least 1 of the following conditions apply:
4.1. Not of childbearing potential, defined as surgically sterile (hysterectomy, bilateral salpingectomy, tubal ligation or bilateral oophorectomy - verbal confirmation through medical history review is acceptable)
4.2. Postmenopausal (no menses for 12 months and confirmed by follicle-stimulating hormone [FSH] level ≥40 mlU/mL)

4.3. Of childbearing potential and agree to practice true abstinence or agree to use a highly effective method of contraception consistently from 30 days prior to the Screening visit until the EOT visit and are required to agree not to donate ova during the trial and for 90 days after the EOT visit

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Any clinically significant medical condition malignancy allergy infection or immunosuppressive condition as determined by the Investigator except cured basal or squamous cell skin cancer
2. Alkaline phosphatase (ALP), aspartate transaminase (AST), alanine transaminase (ALT),and/or total bilirubin >1.5× the upper limit of normal(ULN). Participants with bilirubin >2× ULN that have a documented diagnosis of Gilbert's syndrome can be enrolled at the Investigator's discretion
3. History of malignancy of any organ system (other than localized basal cell carcinoma of the skin or in situ cervical cancer considered treated and cured),treated or untreated, within 5 years before Screening, regardless of whether there is no evidence of local recurrence or metastases
4. Positive for hepatitis B surface antigen (HBsAg),anti-hepatitis C virus (HCV) antibodies, anti-human immunodeficiency virus (HIV) 1 and 2 antibodies, or interferon-gamma release assay (IGRA) for tuberculosis

Date of first enrolment
05/06/2026

Date of final enrolment
03/11/2026

Locations

Countries of recruitment
Australia

Study participating centre

University of Sunshine Coast, Morayfield
Eastwood
Australia
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Sponsor information

Organisation
Fortebioscience

Funder(s)

Funder type

Funder Name
Fortebioscience

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available