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A study in adults who are overweight or obese to assess the safety and effects of a new injectable medicine (PN-477)

Submission date
03/06/2026

Recruitment status
Recruiting

Registration date
05/06/2026

Overall study status
Ongoing

Last Edited
05/06/2026

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
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
A randomized, double-blind, placebo-controlled single-ascending dose study to investigate safety, tolerability, pharmacokinetics and pharmacodynamics of subcutaneous PN-477 in obese or overweight adult participants

Study objectives
Primary: To assess the safety and tolerability of PN-477 following single Subcutaneous administration
Secondary: To assess the pharmacokinetics (PK) of PN-477 following single Subcutaneous administration
Secondary: To assess body weight loss following a single subcutaneous administration with PN-477

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 12/05/2026, Bellberry Human Resource Ethics Committee (Level 1, 196 Greenhill Road, Eastwood, 5063, Australia; +61 08 8361 3222; bellberry@bellberry.com.au), ref: 2026-04-692

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Single

Purpose
Basic science

Study type(s)

Health condition(s) or problem(s) studied
Overweight, obese

Interventions
This is a randomized, double-blind, single-ascending dose study to assess the safety, tolerability, PK and PD of single ascending doses of PN-477. The study consists of 5 planned subcutaneous dosing cohorts comprising 8 participants per cohort.

The starting dose will be multiple folds below the recommended maximum starting dose. Doses will then be increased, depending on safety, tolerability and drug exposure levels in subsequent cohorts. The planned doses may be adjusted in response to the data after a cohort-by-cohort review by the safety review committee. Up to 2 additional cohorts may be added if needed based on the data.

Within each cohort, participants will be randomly assigned to receive PN-477 or matched placebo. The first 2 participants (sentinel participants) in each cohort will be randomized 1:1 to receive PN-477 or placebo on Day 1. These participants will be monitored for 48 hours and, after review of the safety data from both participants and approval by the study Investigator, the additional 6 participants will be randomized to study drug (n=5 PN-477; n=1 placebo).

Randomisation:
Participants will be assigned a unique randomization number and receive their treatment according to a paper randomization schedule that will be provided to the unblinded site pharmacist. Code break envelopes will also be provided to the sites.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
PN-477

Primary outcome(s)
1. Safety and tolerability measured using incidence of adverse events (AEs) at Day 1 through Day 57 (End of Study visit)

Key secondary outcome(s)
1. Pharmacokinetics (PK) of PN-477 measured using maximum observed drug concentration (Cmax), time to Cmax (Tmax) and area under the concentration-time curve (AUC) at Day 1 through Day 43

2. Body weight loss measured using change from baseline body weight and waist circumference at Day 1 through Day 57 (End of Study visit)

Completion date
15/02/2027

Eligibility

Key inclusion criteria
1. Adults aged 18 to 65 years
2. Men and women who are overweight or obese (BMI between 25 and 40 kg/m^2) with a stable body weight for at least 3 months
3. Generally healthy, with no major medical problems based on medical history, physical examination, heart tests, and blood tests
4. Normal or acceptable blood test results, including sugar levels, liver and kidney function, and cholesterol, as assessed by the study doctor
5. Not pregnant or breastfeeding, and willing to use reliable birth control during the study and for a period after the last dose
6. Willing and able to understand the study, sign the consent form, and attend all required study visits

Healthy volunteers allowed

Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Current or past serious medical conditions involving the heart, lungs, liver, kidneys, stomach, intestines, hormones, nervous system, mental health, blood, immune system, or skin
2. Cancer within the past 5 years, except for certain early, fully treated cancers
3. Recent surgery, serious infection, or fever
4. Abnormal blood pressure, heart rate, or heart rhythm test results
5. Severe allergies, serious drug reactions, or sensitivity to the study medicine or its ingredients
6. Use of recreational drugs, excessive alcohol intake, or heavy smoking or nicotine use
7. Recent large blood donation, significant blood loss, or blood transfusion
8. Recent participation in another clinical trial or recent use of an investigational drug or device
9. Inability or unwillingness to follow study instructions or considered unsuitable by the study doctor

Date of first enrolment
24/07/2026

Date of final enrolment
17/12/2026

Locations

Countries of recruitment
Australia

Sponsor information

Organisation
Protagonist Therapeutics, Inc.

Funder(s)

Funder type

Funder Name
Protagonist Therapeutics, Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available