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A three-part study of GM 5022 in healthy adults, looking at safety, side effects, how the body processes the medicine, how the medicine works, and the effects of different doses and food

Submission date 27/04/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/04/2026	**Overall study status** Ongoing	
Last Edited 28/04/2026	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

Study information

Scientific Title
A Phase I three-part study of GM-5022 in healthy volunteers: single ascending dose (randomized placebo controlled); cross-over food effect; and multiple ascending dose (randomized placebo controlled) to investigate the safety, tolerability, pharmacokinetics, pharmacodynamics, and food effect

Study objectives
To investigate the safety, tolerability, pharmacokinetics, pharmacodynamics and food effect of GM-5022.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/04/2026, Advarra Institutional Review Board (IRB) (6100 Merriweather Drive, Columbia, MD 21044, United States of America; +1 (0)410 884 2900; cirbi@advarra.com), ref: Pro00094126

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Single ascending dose; cross-over food effect; and multiple ascending dose

Purpose
Safety, tolerability, pharmacokinetics, pharmacodynamics and food effect

Study type(s)

Health condition(s) or problem(s) studied

Healthy volunteers

Interventions
Part A (single ascending dose [SAD]):
Part A will test single oral doses of GM-5022 in healthy volunteers (HV) in a placebo-controlled, double-blind design. Participants will be randomized to receive a single dose of GM-5022 or placebo (in a 3:1 ratio, the randomisation list will be kept in a secure location until the end of the trial; only the pharmacy staff involved in handling the trial drug will be unblinded during the trial and will have access to the randomization list).

The starting dose of GM-5022 will be 5 mg and subsequent doses will be calculated based on initial data from the first cohort.

Part B (food effect):
Part B will assess the effect of food on the PK of orally administered GM-5022 in HVs. Each participant will have two trial sessions in which they will receive GM-5022. Each participant will receive an oral dose of GM-5022 in the fasted state in one session and in the fed state in the other session; the order will be randomized 1:1. The dosing sessions will be separated by a 1-week washout period.

Part C (multiple ascending dose [MAD]):
Part C will test multiple ascending oral doses of GM-5022 or placebo in HVs in a placebo-controlled, double-blind design. The randomisation list will be kept in a secure location until the end of the trial; only the pharmacy staff involved in handling the trial drug will be unblinded during the trial and will have access to the randomization list. Participants will receive daily oral doses of GM-5022 (or placebo) for 7 days.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
GM-5022

Primary outcome(s)
1. Safety and tolerability measured using adverse events (AEs), laboratory assessments (hematology, serum chemistry, urinalysis), vital signs, 12-lead electrocardiogram (ECG), and emergence of suicidal thoughts and ideations (C-SSRS) at 0-24 h after dosing

2. Pharmacokinetics measured using plasma concentrations of GM-5022 to determine AUC, Cmax, t1/2, Tmax at 0-24 h after dosing

Key secondary outcome(s))

Completion date
31/05/2027

Eligibility

Key inclusion criteria
1. Healthy adult males and females aged 18-55 years, inclusive
2. Body mass index (BMI) of 18.0–30.9 kg/m² (inclusive) at screening
3. Meets the following criteria for psychedelic experience
4. Willing and able to provide informed consent and comply with all trial requirements and study procedures after having discussed the trial with the investigator or their designee
5. Agrees to follow the contraception requirements of the trial (reliable method of contraception for male and female participants)
6. Agrees not to donate blood or blood products during the trial and for up to 3 months after the administration of the trial intervention

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Medical history:
1. Female who is pregnant or lactating, or premenopausal who is sexually active and not using a reliable method of contraception
2. Clinically relevant abnormal history, physical findings, ECG, or laboratory values at screening that could interfere with the objectives of the trial or the safety of the participant
3. Presence of acute or chronic illness or history of chronic illness sufficient to invalidate the participant's participation in the trial or make it unnecessarily hazardous, including impaired endocrine, thyroid, hepatic, respiratory or renal function, diabetes mellitus, or coronary heart disease, hepatitis B or C, or HIV
4. Presence or history of any relevant and/or significant psychiatric history, including personal or family history of psychotic mental illness or mania
5. Surgery (e.g., stomach bypass) or medical condition that might affect absorption of medicines
6. Presence or history of severe adverse reaction to any drug or the excipients present in the capsules
7. Significant risk of suicide, based on a history of suicidal ideation or behavior as assessed by the Columbia Suicide Severity Rating Scale (C-SSRS)
8. Any personal or familial history of epilepsy or other convulsive condition (except history of 1–2 febrile seizures occurring younger than age 5), previous significant head trauma or other factor predisposing to seizures

Date of first enrolment

29/04/2026

Date of final enrolment
29/04/2027

Locations

Countries of recruitment
United States of America

Study participating centre
Prism Research LLC dba Nucleus Network
1000 Westgate Drive, Suite 149
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55114

Sponsor information

Organisation
Gilgamesh Pharma Inc.

Funder(s)

Funder type

Funder Name
Gilgamesh Pharma Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available