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A Phase I randomized study of IMSB301 in healthy volunteers

Submission date 06/08/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 09/08/2024	**Overall study status** Completed	
Last Edited 22/11/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
This study aims to test the safety and effectiveness of an IMSB301, an investigational drug that is being developed to provide a new treatment for patients with type 1 interferonopathy and other autoimmune disorders.

Who can participate?
Healthy volunteers aged 18-55 years

What does the study involve?
Volunteers will be randomly allocated to receive either IMSB301 or a placebo. Each volunteer will provide blood samples to help determine how the drug is processed by their body. The study will include two parts. Volunteers in Part 1 will receive a single dose of the drug on day 1 and be followed for 8 days. Volunteers in Part 2 will receive the drug/placebo twice a day for 7 days and be followed through Day 11. Some volunteers will be selected to receive a single dose of the drug after consuming a high-fat meal to determine the effect food has on how the body processes the drug.

What are the possible benefits and risks of participating?
No medical benefit can be expected for the participants in this study. The potential risks are not known as IMSB301 has not yet been tested in humans; however, based on nonclinical data, the side effects of IMSB301 are expected to be minor.

Where is the study run from?
ImmuneSensor Therapeutics, Inc. (USA)

When is the study starting and how long is it expected to run for?
June 2024 to April 2025

Who is funding the study?
ImmuneSensor Therapeutics, Inc. (USA)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Protocol serial number
IMSB301-101

Study information

Scientific Title
A randomized, double-blind, placebo-controlled Phase I study of single and multiple ascending doses of IMSB301 in healthy subjects

Study objectives
The study is taking place to determine the safety and tolerability of single and multiple-dose orally administered IMSB301 in healthy adult subjects. The study will also evaluate the pharmacokinetics (PK) profile of IMSB301 in plasma including the preliminary effect of a high-fat meal on PK. Finally, the study will evaluate the pharmacodynamic (PD) profile of IMSB301 in whole blood.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/08/2024, Bellberry Limited (123 Glen Osmond Rd, Eastwood SA, 5063, Australia; +61 (0)8 8361 3222; bellberry@bellberry.com.au), ref: 2024-06-811

Study design
Single-center first-in-human randomized double-blind placebo-controlled study in healthy adult male and female subjects

Primary study design
Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied
Healthy male and female adults

Interventions
Part 1 single ascending dose (SAD):
Subjects will be randomized to IMSB301 or placebo within one of five ascending dose cohorts (n = 8 subjects per cohort, assigned 6:2 to active drug and placebo) or until a maximum tolerated dose (MTD) is defined. Additional cohorts (n = 8 per cohort, assigned 6:2 to active drug and placebo) may be added at the discretion of the Safety Review Committee (SRC) if the MTD is not reached and systemic exposures are lower than predicted.

Part 2 multiple ascending dose (MAD):
Subjects will be randomized to receive IMSB301 or placebo within one of three ascending dose cohorts (n = 8 subjects per cohort, assigned 6:2 to active drug and placebo).

Each subject will receive twice daily (BID) oral administration of IMSB301 or placebo on Days 1 through 7 with a single dose the morning of Day 8. The morning and evening doses will be separated by ~12 hours, and administered at approximately the same time daily. On PK intensive days (Day 1 and Day 8), the morning dose will be administered after an 8-hour overnight fast and subjects will remain fasting for 2 hours post-morning dose. For all other morning and evening doses, subjects will be fasted a minimum of 2 hours pre-dose and 1-hour post-dose.

Doses given:
SAD1: 100 mg
SAD2: up to 200 mg
SAD3: up to 400 mg
SAD4: up to 800 mg
SAD5: up to 1600 mg
MAD1: up to 400 mg
MAD2: up to 800 mg
MAD3: up to 1600 mg

Method of randomization:
The participants will be assigned numbers sequentially as they are screened. A randomization schedule will be provided for Part 1 and Part 2, and the participant will receive the study drug regimen assigned to the corresponding randomization number (active or placebo). Randomization will occur either on Day -1 or Day 1 after verification that the subject is eligible for the study. The site will maintain a log for all screened and randomized/enrolled subjects.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
IMSB301

Primary outcome(s)
Safety and tolerability of single and multiple-dose orally administered IMSB301 in healthy adult participants, assessed with physical examination, vital signs (heart rate, blood pressure and body temperature), clinical laboratory tests (hematology, coagulation, biochemistry, and urinalysis), AEs and ECGs at screening, Day -1, Day 1, Day 2, Day 3 and Day 7 for SAD participants and at screening, Day -1, Day 1, Day 2, Day 3, Day 4, Day 5, Day 6 and Day 10 for MAD participants

Key secondary outcome(s))
The pharmacokinetics (PK) profile of IMSB301 in plasma including the preliminary effect of a high-fat meal on PK, measured by comparing plasma concentration versus time profiles of IMSB301 from the analysis of plasma samples. PK parameters will be calculated for each participant on Day 1 pre-dose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10, 12, 16, 24 (Day 2), 36 (Day 2) and 48 (Day 3) hours.

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. Healthy male or female subjects between 18 and 55 years of age, inclusive
2. Signed informed consent and mental capability to understand the informed consent
3. Body mass index (BMI) between 18 and 33 kg/m2, inclusive, and a total body weight >45 kg for females and >50 kg for males
4. Unremarkable physical exam, normal vitals, and all laboratory values must be within normal limits or any abnormalities deemed not clinically significant by the Investigator at screening
5. Electrocardiogram (ECG) without evidence of clinically meaningful conduction abnormalities or active ischemia as determined by the Investigator
6. Negative test for drugs of abuse or alcohol at screening and Day -1
7. Women of childbearing potential (defined as a female who has experienced menarche and who has not undergone successful surgical sterilization [hysterectomy, bilateral salpingectomy, or bilateral oophorectomy]) or is not postmenopausal (defined as amenorrhea for at least 12 consecutive months with an appropriate clinical profile at the appropriate age, eg, greater than 45 years) must have a negative serum pregnancy test at screening and a negative urine pregnancy test on Day -1
8. Male and female subjects with reproductive potential must agree to use highly effective contraception throughout the study and for at least 3 months after the last study drug dose
9. Subjects must be willing and able to comply with scheduled visits, all sample collections, and other trial procedures

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

Key exclusion criteria
1. Resting 12-lead ECG showing confirmed prolongation of corrected QT (QTc) (Fridericia's correction) interval (QTc interval >470 for females and >450 for males)
2. Ongoing illness including, but not limited to, congestive heart failure, unstable angina pectoris, clinically significant cardiac arrhythmia, clinically significant hypertension, or psychiatric illness/social situations that in the opinion of the Investigator would limit compliance with study requirements.
3. Presence of significant gastrointestinal, liver or kidney disease, or any other conditions known to interfere with the absorption, distribution, metabolism or excretion of drugs or known to potentiate or predispose to undesired effects.
4. Have any of the following infectious risks:

4.1. Evidence of active infection during screening or Day -1 that in the opinion of the Investigator would pose an unacceptable risk for participating in the study
4.2. Symptomatic herpes zoster infection within 12 weeks prior to the screening period
4.3. Positive hepatitis B, hepatitis C, human immunodeficiency virus (HIV) or tuberculosis (TB) test at screening
4.4. Household contact with a person with active TB and did not receive appropriate and documented prophylaxis for TB
5. Blood or plasma donation within 30 days prior to Day -1.
6. Any clinically significant illness in the 30 days prior to Day -1.
7. Receipt of an investigational drug within 30 days or five half-lives of the drug (whichever is longer) prior to Day -1.
8. Use of nicotine products within six months prior to screening.
9. Use of prescription drugs except hormonal contraception, or over-the-counter medication including paracetamol, within two weeks of Day -1
10. Prior receipt of investigational product in this trial.
11. Female subjects who are breastfeeding or who have a positive pregnancy test at screening or Day -1.
12. History of any condition that might impair the subject's ability to understand or comply with the requirements of the study or to provide informed consent.
13. Receipt of a vaccination within 3 weeks prior to Day -1.
14. Consumption of any foods or beverages known to modulate CYP enzymes activity (eg, St. John's wort, grapefruit or grapefruit juice, pomelo juice, star fruit, or Seville [blood] orange products) within 72 hours prior to admission to the study site and throughout the study.

Date of first enrolment
01/09/2024

Date of final enrolment
11/02/2025

Locations

Countries of recruitment
Australia

Study participating centre
Scientia Clinical Research
5th Floor, Bright Alliance Building
Corner High and Avoca Street
Randwick
Australia
NSW 2031

Sponsor information

Organisation

ImmuneSensor Therapeutics, Inc.

Funder(s)

Funder type
Industry

Funder Name
ImmuneSensor Therapeutics, Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date