

A Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single- and Multiple-Ascending Doses and Food Effect of BGB-45035 in Healthy Participants and in Adults With Autoimmune Dermatological Diseases

NCT06342713

Status	RECRUITING
Phase	Phase 1
Sponsor	BeiGene
Enrollment	211 participants

Key Eligibility Criteria

Inclusion (15)

- Female or male participants between the ages of 18 and 55 years inclusive (ages 18 and 45 years for Part C).
- BMI of 18 to 32 kg/m²; and a total body weight \geq 50 kg (110 lbs).
- Evidence of a personally signed and dated informed consent document indicating that the participant has been informed of all pertinent aspects of the study.
- Participants who are willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures.
- Nonsterile male participants must be willing to use a highly effective method of birth control and refrain from sperm donation for the duration of the study and for 90 days after the last dose of study drug.

... and 10 more (see full listing online)

Exclusion (8)

- Evidence or history of clinically significant hematological, renal, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, neurologic, or allergic disease (including drug allergies, but excluding untreated, asymptomatic, seasonal allergies at time of dosing).
- Any condition possibly affecting drug absorption (eg, gastrectomy or cholecystectomy).
- Treatment with an investigational drug within 30 days (or as determined by the local requirement) or 5 half-lives preceding the first dose of investigational product, whichever is longer.
- lead ECG demonstrating QTcF \geq 450 milliseconds.
- Clinically significant abnormality on chest radiograph performed at screening or within 3 months of screening date.

... and 3 more (see full listing online)

Locations (13 total)

Innovate Clinical Research, Waitara, New South Wales, Australia
Cmax Clinical Research, Adelaide, South Australia, Australia
Peking University Third Hospital, Beijing, Beijing Municipality, China
... and 10 more locations

<https://clinicaltrials.gov/study/NCT06342713>

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