

A Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Plonmarlimab in Subjects With Acute Gouty Arthritis

NCT07453004

Status	RECRUITING
Phase	Phase 2
Sponsor	TJ Biopharma Co., Ltd.
Enrollment	170 participants

Key Eligibility Criteria

Inclusion (9)

- Subjects aged ≥18 years, regardless of gender.
- Subjects are willing to participate in this study and voluntarily sign the informed consent form.
- Meet the 2015 American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) gout classification criteria.
- Experienced ≥3 episodes of acute gout flare within the 12 months prior to baseline (determination of an acute gout flare based on patient history, referral records, etc., will be made by the investigator).
- Subjects have experienced an acute gout flare within 5 days prior to administration of the investigational product (determination of an acute gout flare based on patient history, referral records, etc., will be made by the investigator).

... and 4 more (see full listing online)

Exclusion (19)

- Secondary gout caused by various etiologies (e.g., gout induced by chemotherapy, judged by the investigator based on the subject's medical history, referral records, etc.).
- History of hypersensitivity to any component of the investigational product or to similar biological agents.
- Contraindication to compound betamethasone therapy.
- Presence of other rheumatic diseases besides gout that may interfere with interpretation of results, including but not limited to rheumatoid arthritis, infectious/suppurative arthritis, traumatic arthritis, etc.
- Pulmonary diseases including but not limited to asthma, chronic obstructive pulmonary disease, interstitial lung disease, pulmonary alveolar proteinosis, pulmonary granulomatosis, etc., or any underlying pulmonary disease that significantly impairs pulmonary function as assessed by the investigator, making the subject unsuitable for this clinical study.

... and 14 more (see full listing online)

Locations (1 total)

Renji Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, Shanghai Municipality, China

<https://clinicaltrials.gov/study/NCT07453004>

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