A Phase 1b/2a Study of Budoprutug in Subjects With Immune Thrombocytopenia (ITP)

NCT07043946

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Climb Bio, Inc.
Enrollment	24 participants

Key Eligibility Criteria

Inclusion (3)

- Aged 18 years at the time of consent.
- Platelet count \< 30,000/µL despite an adequate trial of at least one prior therapeutic attempt. Platelet counts of \< 30,000/µL must be confirmed on 2 occasions at least 5 days apart, but no more than 14 days apart.
- Partial thromboplastin time \< 1.5 x upper limit of normal (ULN), prothrombin time \< 1.5 x ULN, total bilirubin \< 1.5 x ULN unless due to Gilbert's syndrome, or an international normalized ratio \< 1.5 at screening.

Exclusion (9)

- CD19+ B cell count \< 80 cells/µL at Screening, or \< 40 cells/µL if B-cell depleting therapy was received within 24 weeks to 2 years prior.
- Diagnosis of paroxysmal nocturnal hemoglobinuria, Evan's Syndrome, or other bleeding disorders affecting safety or data integrity.
- Prior B-cell depleting therapy (e.g., rituximab) within 24 weeks before first dose or planned during the study.
- Chronic use of anticoagulants or antiplatelet agents (e.g., aspirin, NSAIDs, thienopyridines) within 14 days before dosing through follow-up. Intermittent NSAID use is allowed.
- Immunosuppressants (excluding corticosteroids) within 30 days or 5× half-life before Screening; alkylating agents within 180 days.

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

Locations (20 total)

Climb Bio Investigative Site #359202, Plovdiv, Bulgaria
Climb Bio Investigative Site #359203, Plovdiv, Bulgaria
Climb Bio Investigative Site #359201, Sofia, Bulgaria
... and 17 more locations