Study to Assess the Safety and Tolerability of Tafasitamab in Adult Participants With Primary Autoimmune Blood Cell Disorders

NCT07104565

Status	RECRUITING
Phase	Phase 2
Sponsor	Incyte Corporation
Enrollment	56 participants

Key Eligibility Criteria

Inclusion (18)

- \- Ability to comprehend and willingness to sign a written ICF for the study.
- Aged e 18 years.
- Confirmed historical diagnosis of one of the following autoimmune blood disorders:
- Primary ITP.
- Primary wAIHA.

... and 13 more (see full listing online)

Exclusion (30)

- Clinical manifestations typical for cold agglutinin disease.
- Life-threatening bleeding or urgent need to elevate the platelet count for primary ITP or hemodynamic instability or hemoglobin \< 6 g/dL with urgent need to elevate hemoglobin for primary wAIHA within 2 weeks prior to Day 1.
- Prior treatment with anti-CD19 therapy (eg, mAb, bispecific T-cell engager, or CAR T cell) for any indication.
- Previous severe allergic reaction to a mAb or known allergy to any component/excipient of tafasitamab.
- Changes in doses (\> 10%) of permitted disease-related therapies, including oral corticosteroids and TPO-RA (primary ITP participants) within 2 weeks prior to Day 1, or change in ESA (primary wAIHA participants) dose within 2 weeks prior to Day 1.

... and 25 more (see full listing online)

Locations (40 total)

Palo Verde Cancer Specialists Palo Verde Hematology Oncology, Ltd Glendale, Glendale, Arizona, United States
Usc Norris Comprehensive Cancer Center, Los Angeles, California, United States
Rocky Mountain Cancer Centers, Lone Tree, Colorado, United States
... and 37 more locations