

A Study of Mezagitamab in Adults With Chronic Primary Immune Thrombocytopenia

NCT06722235

Status	RECRUITING
Phase	Phase 3
Sponsor	Takeda
Enrollment	171 participants

Key Eligibility Criteria

Inclusion (6)

- The participant has been diagnosed with ITP that has persisted for at least 12 months.
- The participant's diagnosis of ITP is supported by a prior response to an ITP therapy (not including a thrombopoietin receptor agonist [TPO-RA]), defined as having achieved a platelet count $\geq 50,000/\mu\text{L}$.
- The participant has evidence of insufficient response or intolerance to at least 1 currently available first-line therapy for treatment of ITP (for example, corticosteroids), and at least 1 currently available second-line therapy for treatment of ITP (for example, TPO-RA, rituximab, fostamatinib, mycophenolate). Insufficient response to previous treatment is defined as failure to achieve a sustained platelet count of at least $50,000/\mu\text{L}$ or doubling of baseline platelet count after an appropriate course of prior ITP treatment. Intolerance is defined as a documented side effect causing discontinuation of the therapy.
- The participant has a mean platelet count of $< 30,000/\mu\text{L}$.
- If the participant is receiving allowed standard-of-care treatment for ITP at screening, and continued use is intended, treatment may continue during the trial if the dose, and frequency have been stable for at least 4 weeks before receiving the first dose of IMP (i.e., Day 1), and are expected to remain stable throughout the trial.

... and 1 more (see full listing online)

Exclusion (16)

- The participant has secondary ITP.
- The participant has had any thrombotic or embolic event within 12 months before signing the informed consent form (ICF).
- The participant has had a splenectomy.
- The participant has active infection with hepatitis B virus, hepatitis C virus, or human immunodeficiency virus (HIV).
- History of malignancy (including myelodysplastic syndrome) within 5 years of signing the ICF, except for treated non-melanoma skin cancer or cervical carcinoma in situ.

... and 11 more (see full listing online)

Locations (110 total)

USC Norris Comprehensive Cancer Center - Keck Medicine of USC, Los Angeles, California, United States

Rocky Mountain Cancer Center, Denver, Colorado, United States

Georgetown University Medical Center - Lombardi Comprehensive Cancer Center, Washington D.C., District of Columbia, United States

... and 107 more locations

<https://clinicaltrials.gov/study/NCT06722235>

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