

Safety, Tolerability, and Efficacy of NVG-2089 in Participants With Immune Thrombocytopenia

NCT07095127

Status	RECRUITING
Phase	Phase 2
Sponsor	Navig Therapeutics, Inc.
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (9)

- Males and female participants, age 18 to 80 years at time of screening.
- Diagnosis of persistent (≥ 3 months and ≥ 12 months), or chronic (≥ 12 months) primary ITP. If the participant has received prior treatment for ITP, they must have a history of response to at least one previous therapy (defined as increase in platelet count to $\geq 50,000$ cells/mm³ with an increase of $\geq 20,000$ cells/mm³ relative to platelet count prior to treatment).
- Asymptomatic or with minor mucocutaneous bleeding AND platelet count of $\geq 20,000$ to $\leq 50,000$ cells/mm³, measured on 2 occasions. At least one measurement should be obtained during screening. Documented historical platelet count obtained within 4 weeks prior to screening will also be acceptable for one of the two readings.
- (For US only) If at least one screening platelet count $\geq 30,000$ cells/mm³ and $< 50,000$ cells/mm³, the participant must be on at least 1 other treatment for ITP with insufficient response as evidenced by platelet count $< 50,000$ cells/mm³.
- If participant has received prior IVIg therapy participant must have shown a sufficient platelet response (doubling from baseline platelet count within 7 days of IVIg infusion) and must not have lost response to IVIg therapy while on treatment.

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

Exclusion (31)

- Secondary forms of ITP (e.g., ITP secondary to infection, autoimmune diseases, lymphoproliferative diseases and medications).
- History of splenectomy.
- History of malignancy, unless the participant received treatment with curative intent. Participants with fully excised non-melanoma skin cancer or cervical cancer are allowed.
- History of solid organ transplant.
- Planned or anticipated medical or surgical procedure, including dental procedure, during the timeframe of the study conduct.

... and 26 more (see full listing online)

Locations (1 total)

Navig Site, Westbury, New York, United States