A Study to Assess the Efficacy and Safety of Efgartigimod IV in Adult Participants With Primary Immune Thrombocytopenia

NCT06544499

Status	RECRUITING
Phase	Phase 3
Sponsor	argenx
Enrollment	69 participants

Key Eligibility Criteria

Inclusion (6)

- Is at least 18 years of age and the local legal age of consent for clinical studies when signing the informed consent form (ICF).
- Has documented baseline mean platelet count of \<30 x 10\^9/L before randomization
- Has a documented duration of primary immune thrombocytopenia (ITP) of more than 12 months on the date of informed consent form (ICF) signature.
- Has documented prior ITP treatment with at least 1 of the following treatments: corticosteroids, intravenous immunoglobulin (IVIg), anti-D immunoglobulin, thrombopoietin receptor agonist (TPO-RAs), or rituximab.
- Has documented insufficient response to a prior ITP treatment (the specific criteria can be found in the protocol).

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

Exclusion (5)

- Other than the indication under study, known autoimmune disease or any medical condition that would interfere with an accurate assessment of clinical symptoms of ITP, confound the results of the study or put the participant at undue risk.
- Secondary ITP
- Nonimmune thrombocytopenia
- Autoimmune hemolytic anemia
- ITP-associated critical or severe bleeding The complete list of criteria can be found in the protocol.

Locations (94 total)

Mayo Clinic Hospital Scottsdale, Phoenix, Arizona, United States
University of Southern California Norris Comprehensive Cancer Center, Los Angeles, California, United States
Sharp Memorial Hospital, Oceanside, California, United States
... and 91 more locations