



Clinical Trial for ITP

Amgen 20060131

A Randomized, Controlled, Open-Label Study Evaluating the Efficacy and Tolerability of AMG 531 versus Medical Standard of Care as Chronic Therapy for Non-splenectomized Subjects with Immune (Idiopathic) Thrombocytopenia Purpura

Inclusion Criteria

- Subject \geq 18 years of age; signed informed consent prior to any study specific procedure
- Diagnosis of ITP according to ASH guidelines
- For subjects >60 years of age: require a written bone marrow biopsy report confirming diagnosis of ITP
- Subject has received at least 1 prior ITP treatment
- Platelet count $< 50 \times 10^9/L$ or platelet count falls to $< 50 \times 10^9/L$ during or after a clinically indicated taper or discontinuation of ITP therapy

Exclusion Criteria

- Subject has had a splenectomy for any reason
- Subject has active malignancy
- History of cancer, other than basal cell carcinoma or cervical carcinoma in situ, with treatment or active disease within 5 years
- Subject has a known history of bone marrow stem cell disorder
- Subject has participated in any study evaluating PEG-rHuMGDF, rHuTPO, AMG531, or a thrombopoietic protein
- Subject is receiving other investigational drugs or procedures, or has in last 30 days
- Subject is not using contraception, is pregnant or breastfeeding
- Known sensitivity to any recombinant *E. coli* derived product
- Subject cannot give informed consent or comply with study procedures, for any reason