

Study of PN20 in Adult Patients With Primary Immune Thrombocytopenia (ITP)

NCT06880081

Status	RECRUITING
Phase	Phase 1
Sponsor	Chongqing Peg-Bio Biopharm Co., Ltd.
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (5)

- Aged between 18 and 65 years (inclusive), male or female;
- Diagnosed with primary immune thrombocytopenia (ITP) and have a disease course of more than 6 months;
- Patients who have no response or relapsed after splenectomy. Or patients who have not been splenectomised and have completed at least 1 prior treatment for ITP (such as glucocorticoids, immunoglobulin) and have failed to respond or relapsed after treatment;
- During screening period, the mean of two platelet counts must be $< 30 \times 10^9/L$, with none $> 35 \times 10^9/L$;
- Fully understand and are able to comply with the requirements of the protocol, voluntarily participate and sign the informed consent form.

Exclusion (9)

- History of bone marrow stem cell disorder. Any abnormal bone marrow findings other than typical of ITP.
- Any active malignancy. If prior history of cancer other than basal cell carcinoma or cervical carcinoma in situ, no treatment or active disease within 5 years prior to signing the ICF.
- Diagnosed with arterial thrombotic disease (such as cerebral thrombosis, transient ischemic attack, myocardial infarction, peripheral arterial disease, etc.); Patients with a history or complications of venous thrombosis (such as deep vein thrombosis, pulmonary embolism); or patients who are using anticoagulants or antiplatelet drugs at the beginning of screening.
- Subjects who have used romiplostim or its analogs in the past and have not responded.
- Subjects who have used eltrombopag, haitubopag, avatubopag, recombinant human thrombopoietin (rhTPO), or other drugs with c-MPI stimulating effects within the 4 weeks prior to signing the ICF.

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

Locations (5 total)

Affiliated Hospital of Guizhou Medical University, Guiyang, Guizhou, China
The Second Affiliated Hospital of Nanchang University, Nanchang, Jiangxi, China
Jining First People's Hospital, Jining, Shandong, China
... and 2 more locations

<https://clinicaltrials.gov/study/NCT06880081>

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