Anti-CD38 Monoclonal Antibody Combined With Rituximab in the Management of Primary Immune Thrombocytopenia (ITP)

NCT07362199

Status	RECRUITING
Phase	Phase 2
Sponsor	Institute of Hematology & Blood Diseases Hospital, China
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (8)

- Age e18 years, male or female.
- Before enrollment, the subjects have been clinically diagnosed with primary immune thrombocytopenia for no less than three months according to the American Society of Hematology guidelines 2011 Evidence-Based Practice Guideline (Neunert et al. 2011) or the International Consensus Report for the Investigation and Management of Primary Immune Thrombocytopenia (Provan et al. 2010), as applicable locally.
- Subjects have failed glucocorticoid therapy (either due to inefficacy, efficacy could not be maintained, or relapse). Subjects have failed at least one prior thrombopoietin receptor agonist therapy (such as rhTPO, eltrombopag, hetrombopag, etc.) in second-line treatment, as well as rituximab/anti-CD38 monoclonal antibody therapy (either due to inefficacy, efficacy could not be maintained, or relapse). Alternatively, subjects have experienced treatment failure or post-splenectomy relapse following splenectomy.
- Subjects with a platelet count of \<30×10\^9/L within the 24 hours prior to the first dose of the study drug; The mean platelet count of at least two separate assessments (at least 1 week apart) \<30×10\^9/L during the screening visit, and no platelet count \> 35×10\^9/L.
- ECOG performance status score of d2.

... and 3 more (see full listing online)

Exclusion (26)

- Subjects allergic to CD20 monoclonal antibody or CD38 monoclonal antibody.
- Subjects who are diagnosed with autoimmune hemolytic anemia or various secondary thrombocytopenic disorders.
- Subjects with history of any thrombotic or embolic events or extensive and severe bleeding, such as hemoptysis, major upper gastrointestinal bleeding, intracranial hemorrhage, or the presence of sepsis or other irregular bleeding within the 12 months preceding the initiation of the first dose of study drug.
- Subjects who have participated in any other investigational drug studies (including vaccine studies) or been exposed to other investigational drugs within the first 4 weeks or 5 half-lives (whichever was longer) prior to the first dose of study drug.
- Subjects who have used anticoagulants or any agents with antiplatelet effects, such as aspirin, within 3 weeks prior to the first dose of study drug.

... and 21 more (see full listing online)

Locations (1 total)

Chinese Academy of Medical Science and Blood Disease Hospital, Tianjin, Tianjin Municipality, China