Phase 3 Clinical Project of Pegylated Recombinant Human Coagulation Factor VIII-Fc Fusion Protein

NCT06142552

Status	RECRUITING
Phase	Phase 3
Sponsor	Jiangsu Gensciences Inc.
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (6)

- dage d65 year-old men;
- Patients with clinically confirmed severe hemophilia A, i.e. at screening (central laboratory testing) or previous medical records confirm: Fg activity \< 1%
- Previous documented treatment with any recombinant and/or blood-derived coagulation factor g products or cryoprecipitation products and dosed e150 exposure days (EDse150)
- Normal prothrombin time (PT) or International Normalized Ratio (INR)\<1.3
- Bleeding events were recorded in detail for at least 6 months prior to screening Participants in the on demand /PPX group were required to have at least 6 episodes of spontaneous bleeding within 6 months

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

Exclusion (29)

- Known or suspected allergy to the investigational drug or its excipients, including mouse or hamster proteins;
- Hypersensitivity or anaphylaxis after Fg or IgG2 injection in the past;
- Fg inhibitor positive (e0.6 BU/mL) during the screening period, or have a history of Fg inhibitor positive in the past, or a family history of Fg inhibitor positive;
- Von Willebrand factor (vWF) antigen test results were lower than the lower limit of normal value;
- Severe anemia at the screening stage (hemoglobin \< 60 g/L);

... and 24 more (see full listing online)

Locations (28 total)

Beijing tongren hospital,CMU, Beijing, China
XiangYa Hospital CentralSouth University, Changsha, China
The Second Affiliated Hospital of Chongqing Medical University, Chongqing, China
... and 25 more locations