A Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of NXT007 in Persons With Severe or Moderate Hemophilia A

NCT05987449

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Hoffmann-La Roche
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (10)

- Diagnosis of severe (Factor VIII \[FVIII\] coagulant activity \<1 IU/dL) or moderate (FVIII coagulant activity e1 IU/dL and d5 IU/dL) congenital hemophilia A with or without inhibitors against FVIII
- Participants with FVIII inhibitors: participants using recombinant activated factor VII (rFVIIa) or willing to switch to rFVIIa as primary bypassing agent for the treatment of breakthrough bleeds, trauma, or procedures
- Historic local FVIII inhibitor test results being available during screening to confirm any previous inhibitor history and current status
- Participants who previously successfully completed immune tolerance induction (ITI) must have done so at least 5 years before screening and must have no evidence of inhibitor recurrence (permanent or temporary) since. FVIII tolerance defined as \<0.6 Bethesda unit (BU)/mL (\<1.0 BU/mL only for laboratories with an historical sensitivity cutoff for inhibitor detection of 1.0 BU/mL) and in vivo recovery \>66%
- Documentation of number and type of bleeding episodes in the last 24 weeks prior to enrollment

... and 5 more (see full listing online)

Exclusion (19)

- Inherited or acquired bleeding disorders other than congenital hemophilia A
- Ongoing or planned ITI therapy
- Previous or current treatment for thromboembolic disease (with the exception of previous catheter-associated thrombosis for which anti-thrombotic treatment is not currently ongoing) or signs of thromboembolic disease
- At high risk for thrombotic microangiopathy (TMA), including past personal or family history of TMA, in the investigator's judgment
- For Part 1 only: Personal history of ischemic heart disease, cerebrovascular disease, or diabetes mellitus

... and 14 more (see full listing online)

Locations (13 total)

UC Davis Cancer Center, Sacramento, California, United States
Georgetown Uni Medical Center, Washington D.C., District of Columbia, United States
Indiana Hemophilia & Thrombosis center, Indianapolis, Indiana, United States
... and 10 more locations