

Hämophilie A

Eine Studie zu subkutanem Emicizumab bei Kindern mit Hämophilie A und Faktor-VIII-Hemmkörpern (FVIII)

A Study of Emicizumab Administered Subcutaneously (SC) in Pediatric Participants With Hemophilia A and Factor VIII (FVIII) Inhibitors (HAVEN 2)

Trial Status
Abgeschlossen

Trial Runs In
10 Countries

Trial Identifier
NCT02795767 2016-000073-21
HAVEN2 BH29992

Die Informationen stammen direkt von Websites öffentlicher Register wie ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com usw. und wurden nicht modifiziert.

Official Title:

A Multicenter, Open-Label, Phase III Clinical Trial to Evaluate the Efficacy, Safety, and Pharmacokinetics of Subcutaneous Administration of Emicizumab in Hemophilia A Pediatric Patients With Inhibitors

Trial Summary:

This non-randomized, multicenter, open-label, Phase III clinical study will evaluate the efficacy, safety, and pharmacokinetics of emicizumab administered subcutaneously initially once weekly (QW) in pediatric participants with hemophilia A with FVIII inhibitors. This study will open two additional non-randomized cohorts to investigate once every 2 weeks (Q2W) and once every 4 weeks (Q4W) regimens in pediatric participants.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
All

Age
17 Years

Healthy Volunteers
No

Inclusion Criteria:

ForPatients

by Roche

- Children less than (<) 12 years of age, with allowance for participants 12 to 17 years of age who weigh <40 kilograms (kg) (Cohort A only); and participants <2 years of age will be allowed to participate only after the protocol-defined interim data review criteria are met (Cohort A only)
- Diagnosis of congenital hemophilia A of any severity and documented history of high-titer inhibitor (that is [i.e.], greater than or equal to [\geq] 5 Bethesda units [BU])
- Requires treatment with bypassing agents
- Adequate hematologic, hepatic, and renal function

Exclusion Criteria:

- Inherited or acquired bleeding disorder other than hemophilia A
- Ongoing (or planning to receive during the study) immune tolerance induction (ITI) therapy or prophylaxis treatment with FVIII
- Previous (in the past 12 months) or current treatment for thromboembolic disease or signs of thromboembolic disease
- Other disease that may increase risk of bleeding or thrombosis
- History of clinically significant hypersensitivity associated with monoclonal antibody therapy or components of the emicizumab injection
- Known infection with human immunodeficiency virus (HIV) or hepatitis B or C virus
- Use of systemic immunomodulators at enrollment or planned use during the study period
- Planned surgery (excluding minor procedures such as tooth extraction or incision and drainage) during the study
- Inability (or unwillingness by caregiver) to receive (allow receipt of) blood or blood products (or any standard-of-care treatment for a life-threatening condition)
- Participants who are at high risk for thrombotic microangiopathy (TMA) (e.g., have a previous medical or family history of TMA), in the investigator's judgement