ForPatients
by Roche

Hemophilia A

BH29992: A Study of Emicizumab Administered Subcutaneously (SC) in Pediatric Participants With Hemophilia A and Factor VIII (FVIII) Inhibitors (HAVEN2)

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

Trial Status	Trial Runs In	Trial Identifier
Completed	10 Countries	NCT02795767 2016-000073-21 HAVEN2 BH29992

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

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	Age	Healthy Volunteers
All	# 17 Years	No

Inclusion Criteria:

- 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 [>/=] 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