ForPatients
by Roche

Hemophilia A

A Clinical Trial to Evaluate Prophylactic Emicizumab Versus no Prophylaxis in Hemophilia A Participants Without Inhibitors (HAVEN3)

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Trial Status	Trial Runs In	Trial Identifier
Completed	14 Countries	NCT02847637 2016-000072-17 HAVEN3 BH30071

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 Randomized, Multicenter, Open-Label, Phase III Clinical Trial to Evaluate the Efficacy, Safety, and Pharmacokinetics of Prophylactic Emicizumab Versus no Prophylaxis in Hemophilia A Patients Without Inhibitors

Trial Summary:

This is a randomized, global, multicenter, open-label, Phase 3 clinical study in participants with severe hemophilia A without inhibitors against Factor VIII (FVIII) who are 12 years or older. The study evaluates two prophylactic emicizumab regimens versus no prophylaxis in this population with emphasis on efficacy, safety, and pharmacokinetics.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#12 Years	No

Inclusion Criteria:

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- Body weight >/= 40 kilogram (kg) at the time of screening
- Diagnosis of severe congenital hemophilia A
- Documentation of the details of prophylactic or episodic FVIII treatment and of number of bleeding episodes for at least the last 24 weeks
- Adequate hematologic function
- Adequate hepatic function
- Adequate renal function
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of less than (<) 1 percent (%) per year during the treatment period and for at least 5 elimination half-lives (24 weeks) after the last dose of study drug

Exclusion Criteria:

- Inherited or acquired bleeding disorder other than hemophilia A
- Previous or current treatment for thromboembolic disease or signs of thromboembolic disease
- Conditions that may increase risk of bleeding or thrombosis
- History of clinically significant hypersensitivity associated with monoclonal antibody therapies or components of the emicizumab injection
- Known human immunodeficiency virus (HIV) infection with cluster of differentiation (CD) 4 count <200 cells per microliter (cells/mcL) within 24 weeks prior to screening. Participants with HIV infection who has CD4 greater than (>) 200 and meet all other criteria are eligible
- Use of systemic immunomodulators at enrollment or planned use during the study, with the exception of anti-retroviral therapy
- Participants who are at high risk for thrombotic microangiopathy (TMA) (for example, have a previous medical or family history of TMA), in the investigator's judgment
- Concurrent disease, treatment, or abnormality in clinical laboratory tests that could interfere with the conduct of the study, may pose additional risk, or would, in the opinion of the investigator, preclude the participant's safe participation in and completion of the study
- Planned surgery (excluding minor procedures) during the study
- Receipt of emicizumab in a prior investigational study; an investigational drug to treat or reduce the risk of hemophilic bleeds within 5 half-lives of last drug administration; a non-hemophilia-related investigational drug concurrently, within last 30 days or 5 half-lives, whichever is shorter
- Pregnant or lactating, or intending to become pregnant during the study

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