ForPatients
by Roche

Hemophilia A

A Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Prophylactic Emicizumab Versus no Prophylaxis in Hemophilia A Participants With Inhibitors (HAVEN1)

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Trial Status	Trial Runs In	Trial Identifier
Completed	14 Countries	NCT02622321 2015-002866-21, HAVEN1 BH29884

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This multicenter, open-label study will evaluate the safety, efficacy and pharmacokinetics of prophylactic emicizumab treatment in participants previously treated with episodic or prophylactic bypassing agents. Episodic bypassing agent participants will be randomized in a 2:1 fashion to receive emicizumab prophylaxis (Arm A) versus no prophylaxis (Arm B) and will be stratified across Arms A and B according to the number of bleeds they experienced over the last 24 weeks prior to study entry (less than [<] 9 or greater than or equal to [>/=] 9 bleeds); Arm B participants will have the opportunity to switch to emicizumab prophylaxis after at least 24 weeks on-study. Prophylactic bypassing agent participants will switch to emicizumab prophylaxis (Arm C) from the start of the trial; enrollment will be extended for 24 weeks after the last participant has enrolled in Arms A or B or until approximately 50 participants have enrolled in Arm C, whichever occurs first. Episodic bypassing agent participants who previously participated in the non-interventional study BH29768 (NCT02476942) who were unable to enroll in Arms A or B, or participants on prophylactic bypassing agents who were unable to enroll in Arm C, prior to their closure will have the opportunity to enroll in Arm D. Like participants in Arms A and C, Arm D participants will receive emicizumab prophylaxis from the start of the trial. All participants will continue to receive episodic bypassing agent therapy to treat breakthrough bleeds, preferably with recombinant activated factor VII (rFVIIa).

Hoffmann-La Roche	Phase 3
Sponsor	Phase

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Trial Identifiers

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Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=12 Years	No