



WFH and NBDF statement on severe adverse event with marstacimab rebalancing agent for hemophilia

December 22, 2025

The World Federation of Hemophilia (WFH) and National Bleeding Disorders Foundation (NBDF) have been informed by Pfizer of a severe adverse event that occurred December 14 in an individual on prophylaxis with marstacimab (Hypnavzi®) who had suffered a fatal thrombotic stroke after minor surgery. The individual with hemophilia A and active inhibitors was a participant in Pfizer's marstacimab clinical trial program who had been on marstacimab prophylaxis at the standard maintenance dose (150 mg once weekly) for three years. The thrombotic event occurred during the long-term open label extension (OLE) study. Pfizer is actively gathering information to better understand the causality of the event. Marstacimab is not currently approved by regulatory authorities for use in hemophilia with inhibitors and remains under clinical investigation.

Thrombosis is an adverse event of special interest with marstacimab due to the drug's mechanism of action as a rebalancing agent that targets tissue factor pathway inhibitor (TFPI) to increase thrombin generation for clot formation. Thrombotic events have been observed with other nonfactor hemophilia therapies. The use of marstacimab should include close monitoring for symptoms of thrombosis and other adverse events, especially in surgical settings in combination with clotting factor concentrates or bypassing agents.

Marstacimab was approved by the U.S. Food and Drug Administration (FDA) in October 2024 and the European Medicines Agency (EMA) in November 2024 for routine prophylaxis in adults and adolescents aged 12 years and older with severe hemophilia A or B without inhibitors. It is currently approved in the United States, 27 EU member states, Iceland, Liechtenstein, Norway, UK, Switzerland, Canada, Australia, and Singapore.

The WFH and NBDF are monitoring developments and will update the community as more information becomes available.

See Pfizer's letter on the marstacimab adverse event issued December 22 [here](#).