Global dosing hold in fitusiran trials initiated by Sanofi Genzyme to investigate new adverse events

A joint statement of the World Federation of Hemophilia (WFH), European Haemophilia Consortium (EHC) and National Hemophilia Foundation (NHF)

November 6, 2020 – The WFH, EHC and NHF have learned of and subsequently confirmed a decision by Sanofi Genzyme to initiate a voluntary sponsor-led global dosing hold on its full clinical development program for fitusiran due to the identification of new adverse events.

About fitusiran

Fitusiran is a once-monthly, subcutaneously administered investigational non-factor-replacement therapy that uses an interference mechanism known as small interfering RNA (siRNA) – sometimes known as silencing RNA – to target and reduce antithrombin, thereby promoting sufficient thrombin generation to restore hemostasis and prevent bleeding in patients with hemophilia A or B, with or without inhibitors.

Further Information

The WFH, EHC and NHF believe all relevant parties, including participating physicians and patients, have been informed. We are reporting this information, available in the public domain, in keeping with consensus principles developed at the 2020 Safety Summit hosted by the Hemophilia Federation of America and NHF. We are maintaining close communication with all relevant stakeholders and will share additional information as soon as available.

Resources

Preliminary Executive Summary of 2020 NHF/HFA Safety Summit [PDF]