



Sanofi Alliance Partner Alnylam Provides Update on Fitusiran Development Program

Paris, France – September 7, 2017 - [Sanofi](#) alliance partner Alnylam Pharmaceuticals today provided an update on the clinical development program for fitusiran, an investigational RNAi therapeutic in development for the treatment of hemophilia A and B with or without inhibitors. Sanofi has an alliance with Alnylam Pharmaceuticals to co-develop and co-commercialize fitusiran. Alnylam has primary responsibility for execution of the development program.

As disclosed by Alnylam, a fatal thrombotic event occurred in a patient with hemophilia A without inhibitors enrolled in the Phase 2 Open Label Extension (OLE) study of fitusiran. As a result, Alnylam, the sponsor of this study, has suspended dosing in all ongoing fitusiran studies pending further review of the safety event and development of a risk mitigation strategy. Based on overall consideration of fitusiran's benefit-risk profile, Alnylam aims to resume dosing as soon as it is feasible upon agreement with global regulatory authorities and with appropriate protocol amendments for enhanced patient safety monitoring in place.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Consumer Healthcare. Sanofi is listed in Paris (EURONEXT: [SAN](#)) and in New York (NYSE: [SNY](#)).

Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2016. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Contacts:

Media Relations

Ashleigh Koss
Tel. : +1 908 981 8745
Ashleigh.Koss@sanofi.com

Investor Relations

George Grofik
Tel.: +33 (0)1 53 77 45 45
ir@sanofi.com