



Press Release

Source: Sanofi (EURONEXT: SAN) (NYSE: SNY)

Sanofi and Alnylam enter into strategic restructuring of RNAi therapeutics rare disease alliance

- * Restructuring enables streamlined development and optimization of commercial opportunities for ATTR amyloidosis and hemophilia programs
- * Sanofi obtains global rights for investigational therapeutic fitusiran in hemophilia and other rare bleeding disorders
- * Alnylam obtains global rights for investigational ATTR amyloidosis programs: patisiran and ALN-TTRsc02

Paris and Cambridge, Mass. – January 7, 2018 –[Sanofi](#) and [Alnylam Pharmaceuticals, Inc.](#) (Nasdaq: ALNY), the leading RNAi therapeutics company, announced today a strategic restructuring of their RNAi therapeutics alliance to streamline and optimize development and commercialization of certain products for the treatment of rare genetic diseases. Specifically:

- Sanofi will obtain global development and commercialization rights to fitusiran, an investigational RNAi therapeutic, currently in development for the treatment of people with hemophilia A and B. Global commercialization of fitusiran, upon approval, will be done by Sanofi Genzyme, the specialty care global business unit of Sanofi. Alnylam will receive royalties based on net sales of fitusiran products.
- Alnylam will obtain global development and commercialization rights to its investigational RNAi therapeutics programs for the treatment of ATTR amyloidosis, including patisiran and ALN-TTRsc02. Sanofi will receive royalties based on net sales of these ATTR amyloidosis products.
- With respect to other products falling under the RNAi therapeutics alliance, the material terms of the 2014 Alnylam-Sanofi Genzyme alliance remain unchanged.

“The restructured alliance reflects Sanofi Genzyme’s sustained interest in the strong potential of Alnylam’s portfolio of genetic medicines. The new structure simplifies operations, providing both parties the agility needed to make these medicines available to patients as quickly as possible once approved,” said Bill Sibold, Executive Vice President and Head of Sanofi Genzyme. “This restructuring will enable both parties to maximize the value of each asset and allows us to maintain shared economics across the alliance program.”

Fitusiran complements Sanofi Genzyme’s rare hematology portfolio, and creates a focus on bringing an innovative product to market globally, upon approval, for people living with hemophilia, one of the most common rare diseases.

“This strategic restructuring enables streamlined development and an optimized approach to bringing innovative medicines to patients with ATTR amyloidosis and hemophilia around the world, maximizing the commercial opportunities for these programs,” said John Maraganore, Ph.D., Chief

Executive Officer of Alnylam. “For Alnylam, this provides strategic clarity and operational alignment with regard to the development and commercialization of patisiran and ALN-TTRsc02. This will allow us to develop both products in a comprehensive manner, potentially addressing the full spectrum of transthyretin-mediated amyloidosis disease treatment and prevention. At the same time, we will continue to support and benefit – via royalties – from the fitusiran opportunity through Sanofi’s significant development and commercial leadership.”

This restructuring provides Alnylam with the opportunity to consolidate its ATTR amyloidosis business to maximize its value, and the opportunity for near-term acceleration of product revenue growth based on newly obtained rights to commercialize patisiran around the world, once approved. In addition, it enables Alnylam to build a global presence and commercial infrastructure that can be leveraged for ALN-TTRsc02 and additional programs, including givosiran, an investigational RNAi therapeutic for the treatment of acute hepatic porphyrias, and cemdisiran, an investigational RNAi therapeutic for the treatment of complement-mediated diseases – where Alnylam has retained global ownership.

Terms of the Agreements

Fitusiran

The restructuring will enable Sanofi to assume full responsibility for development and commercialization of fitusiran, including costs. However, during the anticipated transition period Alnylam will fund such costs. Alnylam intends to substantially complete the transition of fitusiran to Sanofi by mid-2018. Sanofi will pay Alnylam a milestone of \$50 million following dosing of the first patient in the ATLAS Phase 3 program for fitusiran.

Patisiran and ALN-TTRsc02

Alnylam will fund all development and commercialization costs for patisiran and ALN-TTRsc02 going forward. There will be no additional milestones due to either company with respect to patisiran or ALN-TTRsc02.

Sanofi intends to substantially complete the transition of its patisiran activities in regions outside the United States, Canada, and Western Europe, consistent with the original scope of its license rights to patisiran, by mid-2018.

Product royalties

Sanofi Genzyme and Alnylam will be eligible to receive tiered royalties of 15 to 30 percent on global net sales of ALN-TTRsc02 and fitusiran, respectively, upon approval and commercialization. Previously, these programs were subject to co-development and co-commercialization terms in the United States, Canada and Western Europe.

For patisiran, Sanofi Genzyme will be eligible to receive royalties, increasing over time to up to 25 percent, on sales in territories excluding the United States, Canada, and Western Europe.

Sanofi continues to have the right to opt into other Alnylam rare genetic disease programs for development and commercialization in territories outside of the United States, Canada and Western Europe, as well as one right to a global license.

The transaction is subject to customary closing conditions and clearances, including clearance under the Hart-Scott Rodino Antitrust Improvements Act.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare

diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi Genzyme focuses on developing specialty treatments for debilitating diseases that are often difficult to diagnose and treat, providing hope to patients and their families. Learn more at www.sanofigenzyme.com.

Sanofi, Empowering Life

About Alnylam Pharmaceuticals

Alnylam (Nasdaq: ALNY) is leading the translation of RNA interference (RNAi) into a whole new class of innovative medicines with the potential to transform the lives of people afflicted with rare genetic, cardio-metabolic, and hepatic infectious diseases. Based on Nobel Prize-winning science, RNAi therapeutics represent a powerful, clinically validated approach for the treatment of a wide range of severe and debilitating diseases. Founded in 2002, Alnylam is delivering on a bold vision to turn scientific possibility into reality, with a robust discovery platform and deep pipeline of investigational medicines, including four product candidates that are in late-stage development. Looking forward, Alnylam will continue to execute on its "Alnylam 2020" strategy of building a multi-product, commercial-stage biopharmaceutical company with a sustainable pipeline of RNAi-based medicines to address the needs of patients who have limited or inadequate treatment options. Alnylam employs over 700 people in the U.S. and Europe and is headquartered in Cambridge, MA. For more information about our people, science and pipeline, please visit www.alnylam.com and engage with us on Twitter at [@Alnylam](https://twitter.com/Alnylam) or on [LinkedIn](https://www.linkedin.com/company/alnylam).

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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.

Alnylam Forward Looking Statements

Various statements in this release concerning Alnylam's future expectations, plans and prospects, including without limitation, Alnylam's views with respect to the potential for streamlined development and an optimized approach to bringing innovative medicines to patients with ATTR amyloidosis and hemophilia around the world, maximizing the commercial opportunities for these programs under the restructured alliance with Sanofi Genzyme, the development of patisiran and ALN-TTRsc02 in a comprehensive manner, addressing the full spectrum of transthyretin-mediated amyloidosis disease treatment and prevention, expectations regarding a potential milestone payment and potential royalty payments under the restructured alliance, and expectations regarding its "Alnylam 2020" guidance for the advancement and commercialization of RNAi therapeutics, constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Actual results and future plans may differ materially from those indicated by these forward-looking statements as a result of various important risks, uncertainties and other factors, including, without limitation, Alnylam's ability to discover and develop novel drug candidates and delivery approaches, successfully demonstrate the efficacy and safety of its product candidates, the pre-clinical and clinical results for its product candidates, which may not be replicated or continue to occur in other subjects or in additional studies or otherwise support further development of product candidates for a specified indication or at all, actions or advice of regulatory agencies, which may affect the design, initiation, timing, continuation and/or progress of clinical trials or result in the need for additional pre-clinical and/or clinical testing, delays, interruptions or failures in the manufacture and supply of its product candidates, obtaining, maintaining and protecting intellectual property, Alnylam's ability to enforce its intellectual property rights against third parties and defend its patent portfolio against challenges from third parties, obtaining and maintaining regulatory approval, pricing and reimbursement for products, progress in establishing a commercial and ex-United States infrastructure, competition from others using technology similar to Alnylam's and others developing products for similar uses, Alnylam's ability to manage its growth and operating expenses, obtain additional funding to support its business activities, and establish and maintain strategic business alliances and new business initiatives, Alnylam's dependence on third parties for development, manufacture and distribution of products, the outcome of litigation, the risk of government investigations, and unexpected expenditures, as well as those risks more fully discussed in the "Risk Factors" filed with Alnylam's most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings that Alnylam makes with the SEC. In addition, any forward-looking statements represent Alnylam's views only as of today, and should not be relied upon as representing its views as of any subsequent date. Alnylam explicitly disclaims any obligation, except to the extent required by law, to update any forward-looking statements.