Press Release: Nirsevimab: Sanofi, AstraZeneca and Sobi simplify contractual agreements

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BY SANOFI

Nirsevimab: Sanofi, AstraZeneca and Sobi simplify contractual agreements

- Modification of existing collaboration agreement with AstraZeneca gives Sanofi full commercial control of nirsevimab and enhanced agility in the U.S.

- Existing collaboration agreement with AstraZeneca remains in place for nirsevimab activities ex-U.S.

Paris, April 11, 2023. Sanofi has simplified its contractual arrangements relating to the development and commercialization of Beyfortus (nirsevimab) in the United States (U.S.).

Under the new and updated arrangements, Sobi will terminate its participation agreement with AstraZeneca, and Sanofi and AstraZeneca will update the Collaboration Agreement so that Sanofi has full commercial control of nirsevimab in the U.S. Sanofi has simultaneously entered into a direct royalty agreement with Sobi to share a portion of U.S. net sales from nirsevimab.

With respect to territories outside the U.S., the existing Collaboration Agreement between AstraZeneca and Sanofi continues to govern that relationship.

The new and updated contractual agreements do not impact nirsevimab registration and launch in the U.S., where all parties remain committed to making Beyfortus available for all infants in time for the 2023/24 RSV season.

Beyfortus® (nirsevimab), an investigational long-acting antibody designed to protect all infants against RSV infections from birth through their first RSV viral season with a single dose, is being co-

developed by Sanofi and AstraZeneca. Beyfortus was developed to provide direct antibody protection to newborns and infants and protect them against lower respiratory tract infections caused by RSV. Monoclonal antibodies do not require activation of the immune system to confer direct and rapid protection against infection. Beyfortus has received marketing authorization in the European Union for the prevention of lower respiratory tract disease caused by RSV in neonates and infants from birth during their first RSV season.

In March 2017, AstraZeneca and Sanofi announced an agreement for the development and commercialization of Beyfortus. Under the agreement, AstraZeneca leads all development and manufacturing activities, while Sanofi is responsible for marketing activities and revenue recognition. Under the terms of the global agreement, Sanofi has made an upfront payment of €120 million, a milestone payment of €30 million and a regulatory payment of €25 million. Sanofi shall pay up to €440 million, subject to the achievement of a certain number of regulatory and sales objectives. Both companies share costs and benefits related to the Alliance in certain territories.

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people’s lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. The risks and uncertainties also include the uncertainties 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, 2022. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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