

Sanofi signs strategic deal for exclusive US over-the-counter rights to Tamiflu[®] in Flu Care

PARIS – July 23, 2019 – Sanofi signed an agreement with Roche for the exclusive over-the-counter (OTC) rights to Tamiflu[®] for the prevention and treatment of influenza or flu in the US. Under the terms of the agreement, Sanofi will be responsible for leading FDA negotiations for the OTC switch and subsequent exclusive marketing, scientific engagement and distribution of Tamiflu OTC in the US. Tamiflu is currently sold in the US by Genentech, a member of the Roche Group, for prescription use.

“This is a strategic and important transaction for us as we strive to continually bring innovations to the market,” says Alan Main, Executive Vice President, Consumer Healthcare, Sanofi. “The US market is the largest OTC market in the world and a successful switch of Tamiflu to OTC would support our global cough and cold strategy by expanding into flu with a sustainable point of difference in the market. Tamiflu will offer a significant public health benefit once switched by providing increased access to a safe and efficacious treatment for the prevention and treatment of flu. People would be able to either reduce their chances of getting the flu or, at the first signals, appropriately treat as early as possible during the crucial first 48 hours without having to wait for a doctor’s appointment.”

Flu is a condition for which there is no effective OTC anti-viral treatment. Currently consumers are only able to treat flu symptoms with the available OTC products. Early treatment will help prevent unnecessary spread of the disease. According to the Centers for Disease Control and Prevention (CDC), over 31 million people in the US suffer from the flu in the US each year, but only about 7 million were treated with an effective product like Tamiflu in 2017.

Under the agreement, in addition to leading the FDA negotiations, Sanofi will be responsible for leading the clinical program and funding all studies needed to support the OTC switch in the US in consultation with leading experts in the field. Roche will continue to market Tamiflu in the rest of the world. Sanofi will retain the rights to first negotiations for switch rights in other selected markets.

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, Empowering Life

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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, to complete related transactions 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, 2018. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.