SANOFI

Press Release

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

FDA to review MenQuadfi™ [1], a meningococcal vaccine candidate

PARIS – June 27, 2019 - The U.S. Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) for Sanofi's MenQuadfi™ Meningococcal (Groups A, C, Y, W) Polysaccharide Tetanus Toxoid Conjugate Vaccine candidate to help prevent meningococcal meningitis. The target action date for the FDA decision is April 25, 2020.

The recently submitted BLA includes positive data from Phase II and Phase III clinical trials held in the U.S. to seek an indication for use of the vaccine in persons 2 years of age and older. If approved, MenQuadfi will be available in a fully liquid presentation.

Phase II and Phase III trials have been performed in the U.S., the European Union (EU), Asia and Latin America. Sanofi is conducting additional Phase III trials in these same regions and Africa. The ongoing clinical development program includes different ages ranging from infants 6 weeks of age through older adults. Given the different vaccines schedules in the U.S. and worldwide, the program's objective is to assess the vaccine's ability to help protect individuals from meningococcal meningitis, and address the worldwide needs for meningococcal disease prevention across a broad age range. MenQuadfi's safety and efficacy data have not yet been evaluated by any regulatory authority.

Sanofi's legacy includes more than 40 years at the forefront in helping prevent meningococcal disease, a rare but potentially deadly bacterial infection. Hundreds of cases of meningococcal disease occur throughout the U.S. annually and no one can predict where or when those cases will occur.

[1] Meningococcal (Groups A, C, Y, W) Polysaccharide Tetanus Toxoid Conjugate Vaccine is an investigational drug and is under regulatory review by the U.S. Food and Drug Administration (FDA). The FDA have conditionally accepted MenQuadfi ™ as the trade name for Meningococcal (Groups A, C, Y, W) Polysaccharide Tetanus Toxoid Conjugate Vaccine.

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 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.