Sanofi US reaches settlement agreement to resolve allegations related to patient assistance

CAMBRIDGE, Mass., Feb. 28, 2020 /PRNewswire/ -- Sanofi U.S. today announced that it has reached an $11.85 million settlement agreement with the federal government to resolve an investigation relating to certain financial donations made in 2015 and 2016 to an independent charity patient assistance foundation that aided patients living with multiple sclerosis.

As part of the settlement, Sanofi U.S. has also entered into a Corporate Integrity Agreement (CIA) with the Office of the Inspector General of the U.S. Department of Health and Human Services. Many of the requirements are already incorporated into the Company's existing U.S. compliance program. Sanofi is committed to compliance, and the Company's compliance program is regularly enhanced to ensure its controls meet or exceed the complex and evolving legal, regulatory, and industry requirements, as well as the expectations of patients and providers.

This resolution reflects the Company's desire to put this investigation behind it and to continue its focus on the needs of patients. It does not constitute any admission of guilt.

Sanofi believes all individuals deserve access to medicines prescribed by their physicians. Donations to independent charitable organizations can provide significant assistance to patients with their co-payments for prescriptions, and the Company believes these programs help patients lead healthier lives. Sanofi U.S. continues to donate to independent charity patient assistance foundations as part of its efforts to help ensure patients have access to important medicines as well as maintains other programs to assist patients in this regard.

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.

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