SANOFI

Press Release

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

Sanofi provides update on Zynquista™ (sotagliflozin) type 2 diabetes Phase 3 program and collaboration with Lexicon

PARIS – July 26, 2019 – Sanofi today announced topline results from three Phase 3 trials of Zynquista™ (sotagliflozin) in adults living with type 2 diabetes from the InSynchrony clinical program. Given the primary endpoint results of blood sugar control (HbA1c) reduction in the SOTA-CKD3 and SOTA-CKD4 studies, Sanofi provided notice to Lexicon that it is terminating the collaboration to develop, manufacture, and commercialize Zynquista in all ongoing global type 1 and type 2 diabetes programs.

At this time, the ongoing Phase 3 clinical trials will continue and there will be no immediate changes. Sanofi has expressed willingness to work with Lexicon to ensure a smooth transition of the studies. Sanofi remains committed to working and supporting the investigators and patients enrolled in the studies while next steps are discussed with Lexicon.

Topline results of the three studies are as follows:

- In SOTA-MET, Zynquista (400 mg) demonstrated a statistically significant reduction in HbA1c compared to placebo at 26 weeks in patients on metformin.
- In SOTA-CKD3, Zynquista (400 mg) showed a statistically significant reduction in HbA1c in the entire population of patients with moderate (stage 3) chronic kidney disease (CKD) and in the subpopulation of patients with a glomerular filtration rate of 45-<60 mL/min/1.73m2 (stage 3A CKD) compared to placebo at 26 weeks. However, a statistically significant reduction in HbA1c was not achieved in the subpopulation of patients with a glomerular filtration rate of 30-<45 mL/min/1.73m2 (stage 3B CKD).
- In SOTA-CKD4, Zynquista (200 mg and 400 mg) did not demonstrate a statistically significant reduction in HbA1c, compared to placebo at 26 weeks in patients with CKD4.

No imbalances or new safety signals were observed in these studies.

About Zynquista™ (sotagliflozin)

Zynquista is an oral dual inhibitor of two proteins responsible for glucose regulation known as sodium-dependent glucose co-transporter types 1 and 2 (SGLT1 and SGLT2). SGLT1 is responsible for glucose absorption in the gastrointestinal tract, and SGLT2 is responsible for glucose reabsorption by the kidney. Zynquista is approved in the European Union (EU) for use as an adjunct to insulin therapy to improve blood sugar (glycemic) control in adults with type 1 diabetes mellitus with a body mass index ≥ 27 kg/m^2, who have failed to achieve adequate glycemic control despite optimal insulin

therapy. Outside of such approval in the EU, Zynquista is investigational and not approved by any other regulatory authority for type 1 or type 2 diabetes.

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.