SANOFI

Press Release

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

FDA advisory committee votes on Zynquista™ (sotagliflozin) as treatment for adults with type 1 diabetes

PARIS and THE WOODLANDS, TX – January 17, 2019 – The Endocrinologic and Metabolic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) today voted eight to eight on the question of whether the overall benefits of Zynquista™* (sotagliflozin) outweighed the risks to support approval. Sotagliflozin is an investigational oral dual SGLT1 and SGLT2 inhibitor under regulatory review as an adjunct to insulin for the treatment of adults with type 1 diabetes (T1D). While the FDA is not required to follow the committee's vote, the agency considers the committee's recommendations when making its decision, which is anticipated by March 22, 2019.

Sotagliflozin, developed by Sanofi and Lexicon, has the potential to be the first oral antidiabetic drug approved in the United States together with insulin therapy to improve glycemic (blood sugar) control in adults with T1D.

> *"We believe in the overall benefit-risk profile of sotagliflozin for adults with type 1 diabetes who lack adequate glycemic control using insulin alone,"* said Rachele Berria, MD, PhD, Global Vice President and Head of Diabetes Medical Affairs, Sanofi. *"We will continue to work with the FDA through its review process to hopefully bring to patients a new treatment that can help people living with type 1 diabetes control their blood sugar and address some of the challenges of insulin-only therapy."*

Sotagliflozin is an investigational 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. About 1.3 million Americans have T1D and an estimated 40,000 people will be newly diagnosed each year in the U.S., according to the American Diabetes Association.

> *"In clinical trials, when used in combination with insulin therapy, sotagliflozin significantly improved glycemic control without increasing hypoglycemia,"* said Pablo Lapuerta, MD, Executive Vice President and Chief Medical Officer, Lexicon. *"These results could not be achieved with insulin alone. Diabetic ketoacidosis is an inherent risk of type 1 diabetes and an increase was seen with sotagliflozin compared to insulin alone. We believe this can potentially be addressed with proper education and monitoring."*

The New Drug Application for sotagliflozin included data from the inTandem clinical trial program, which included three Phase 3 clinical trials assessing the safety and efficacy of

sotagliflozin in approximately 3,000 adults with inadequately controlled T1D. The safety and efficacy data have not yet been fully evaluated by any regulatory authority.

Sanofi also submitted a regulatory application to the European Medicines Agency (EMA) in 2018. An EMA approval decision is expected in the first half of 2019.

About Lexicon Pharmaceuticals

Lexicon (NASDAQ: LXRX) is a fully integrated biopharmaceutical company that is applying a unique approach to gene science based on Nobel Prize-winning technology to discover and develop precise medicines for patients with serious, chronic conditions. Through its Genome5000™ program, Lexicon scientists have studied the role and function of nearly 5,000 genes over the last 20 years and have identified more than 100 protein targets with significant therapeutic potential in a range of diseases. Through the precise targeting of these proteins, Lexicon is pioneering the discovery and development of innovative medicines to safely and effectively treat disease. In addition to its first commercial product, XERMELO® (telotristat ethyl), Lexicon has a pipeline of promising drug candidates in clinical and pre-clinical development in diabetes and metabolism and neuropathic pain. For additional information please visit www.lexpharma.com.

*Sotagliflozin is an investigational drug and is under regulatory review by the European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA). The EMA and FDA have conditionally accepted Zynquista™ as the trade name for sotagliflozin.

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, 2017. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Lexicon Forward-Looking Statements

This press release contains "forward-looking statements," including statements relating to Lexicon's and Sanofi's clinical development of and regulatory filings for Zynquista (sotagliflozin) and the potential therapeutic and commercial potential of Zynquista. In addition, this press release also contains forward-looking statements relating to Lexicon's growth and future operating results, discovery, development and commercialization of products, strategic alliances and intellectual property, as well as other matters that are not historical facts or information. All forward-looking statements are based on management's current assumptions and expectations and involve risks, uncertainties and other important factors, specifically including the risk that the FDA and other regulatory authorities may not grant regulatory approval of Zynquista in accordance with Lexicon's currently anticipated timelines or at all, and the risk that such regulatory approvals, if granted, may have significant limitations on the approved use of Zynquista. As a result, Zynquista may never be successfully commercialized. Other risks include Lexicon's ability to meet its capital requirements, successfully commercialize XERMELO (telotristat ethyl), successfully conduct preclinical and clinical development and obtain necessary regulatory approvals of LX2761, LX9211 and its other potential drug candidates on its anticipated timelines, achieve its operational objectives, obtain patent protection for its discoveries and establish strategic alliances, as well as additional factors relating to manufacturing, intellectual property rights, and the therapeutic or commercial value of its drug candidates. Any of these risks, uncertainties and other factors may cause Lexicon's actual results to be materially different from any future results expressed or implied by such forward-looking statements. Information identifying such important factors is contained under "Risk Factors" in Lexicon's annual report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission. Lexicon undertakes no obligation to update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.