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Press Release

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CHMP recommends Zynquista™ (sotagliflozin) for the treatment of adults with type 1 diabetes

PARIS and THE WOODLANDS, TX – March 1, 2019 - The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion on the Marketing Authorization of Zynquista™* (sotagliflozin), developed by Sanofi and Lexicon.

The CHMP recommended approval of sotagliflozin in the European Union (EU) in both a 200-mg and 400-mg dose for use as an adjunct to insulin therapy to improve blood sugar (glycemic) control in adults with type 1 diabetes (T1D) mellitus with a body mass index ≥ 27 kg/m^2, who have failed to achieve adequate glycemic control despite optimal insulin 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).[1] SGLT1 is responsible for glucose absorption in the gastrointestinal tract,[2] and SGLT2 is responsible for glucose reabsorption by the kidney.[3]

The CHMP opinion is based on evidence including 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. These three trials demonstrated that treatment with sotagliflozin, when given to adults with inadequately controlled T1D as an oral adjunct to insulin, resulted in consistent, significant reductions from baseline at 24 weeks in average blood sugar (HbA_{1c}), body weight, systolic blood pressure and a significant improvement of time in target blood sugar range, versus insulin alone, at both 200-mg and 400-mg doses.[4-7]

The European Commission is expected to make a final decision on the Marketing Authorization Application for sotagliflozin in the EU in the coming months.

Sotagliflozin is also currently being reviewed by the U.S. Food and Drug Administration (FDA) and has the potential to be the first oral antidiabetic drug approved in the U.S. for use together with insulin therapy to improve glycemic control in adults living with T1D. The target FDA action date under the Prescription Drug User Fee Act (PDUFA) is anticipated to be March 22, 2019.[8]

* The EMA and FDA have conditionally accepted Zynquista™ as the trade name for sotagliflozin.

References

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8. Sanofi press release, "FDA advisory committee votes on Zynquista™ (sotagliflozin) as treatment for adults with type 1 diabetes". Available via http://hugin.info/152918/R/2231739/877460.pdf [Accessed February 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.

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.

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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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic conditions, as well as those risks 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.