SANOFI

Press Release

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

Zynquista™ now approved in the European Union for treatment of adults with type 1 diabetes

PARIS and THE WOODLANDS, TX – April 26, 2019 - The European Commission has granted marketing authorization for Zynquista™ (sotagliflozin)*, developed by Sanofi and Lexicon. Zynquista is now approved in the European Union, at once-daily doses of 200 mg and 400 mg, for use as an adjunct to insulin therapy to improve blood sugar (glycemic) control in adults with type 1 diabetes (T1D) mellitus and a body mass index ≥ 27 kg/m^2, who could not achieve adequate glycemic control despite optimal insulin therapy.

> "*Millions of people across Europe who live with type 1 diabetes struggle to control their blood sugar, even with optimal insulin therapy,*" commented Thomas Danne, Professor of Pediatrics, Children's Hospital 'Auf der Bult,' Hannover, Germany. "*For the many people living with type 1 diabetes who are overweight or obese, Zynquista will offer a new treatment option physicians can now consider in combination with insulin therapy for appropriate patients.*"

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).[1] SGLT1 is responsible for glucose absorption in the gastrointestinal tract,[2] and SGLT2 is responsible for glucose reabsorption by the kidney.[3]

> "*Zynquista's dual mechanism of action provides important treatment benefits for adults with type 1 diabetes, including reducing blood sugar reabsorption in the kidneys through SGLT2 inhibition and delaying dietary sugar absorption through local SGLT1 inhibition in the intestinal tract,*" added John Reed, M.D., Ph.D., Global Head of Research & Development, Sanofi.

The marketing authorization 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, involving approximately 3,000 adults with inadequately controlled T1D.[4-7]

> *"We are proud to have developed Zynquista in combination with insulin through the largest Phase 3 clinical trial program to date in adults with type 1 diabetes, and now to have it approved in the European Union,"* said Pablo Lapuerta, M.D., Executive Vice President and Chief Medical Officer, Lexicon. *"We thank the European Commission for recognizing the clinical benefits of Zynquista for adults with type 1 diabetes and the families and physicians who participated in the clinical trials."*

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

and significant reductions from baseline at 24 weeks in average blood sugar (HbA_{1c}), body weight, systolic blood pressure, a significant improvement of time in target blood sugar range and improved patient-reported outcomes, versus insulin alone, at both 200-mg and 400-mg doses.[4-7] This was achieved without the usual increase in severe hypoglycemia that comes with intensification of insulin and with less events of severe hypoglycemia in the 400-mg dose at 52 weeks.

Consistent with selective SGLT2 inhibitors, clinical trials with sotagliflozin showed an increased risk of genital mycotic infections and diabetic ketoacidosis (DKA), which is acknowledged to affect people with T1D more frequently than those with type 2 diabetes (T2D). Several leaders in the diabetes scientific community consider the risk of DKA associated with SGLT inhibitors manageable with appropriate patient selection, education and ketone monitoring in place.[8-11] The risk of DKA will be addressed by careful selection of patients for treatment with sotagliflozin and through a risk-management plan and a mitigation strategy, including patient, healthcare professional and care giver educational activities, that will support its safe use.

Zynquista is also currently being evaluated in a program of 11 clinical trials in adults with T2D, including two trials in people living with T2D and renal impairment, and two large cardiovascular outcomes trials.

**Zynquista™ (sotagliflozin) is not currently approved for use in any other markets, where it is considered an investigational product.*

References

1. Lapuerta P, et al. Diabetes and Vascular Disease Research. 2015;12(2):101-10, DOI: 10.1177/1479164114563304.
2. Hummel CS et al. Am J Physiol Cell Physiol 2011;300(1):C14-C21, DOI: 10.1152/ajpcell.00388.2010.
3. Wright EM et al. Physiol Rev 2011;91:733–794.
4. Buse JB et al, Diabetes Care 2018 Jun; dc180343. https://doi.org/10.2337/dc18-0343.
5. Danne T et al, Diabetes Care 2018 Jun; dc180342. https://doi.org/10.2337/dc18-0342.
6. Garg SK et al, N Engl J Med 2017; 377:2337-2348, DOI: 10.1056/NEJMoa1708337.
7. Danne T et al. "inTandem1 and inTandem2: increased time in range with sotagliflozin as adjunct therapy to insulin in adults with type 1 diabetes by 24-week continuous glucose monitoring", Abstract #610, presented at European Association for the Study of Diabetes 54th Annual Meeting, October 1-5, 2018, Berlin, Germany. Available via https://www.easd.org/virtualmeeting/home.html#!resources/intandem1-and-intandem2-increased-time-in-range-with-sotagliflozin-as-adjunct-therapy-to-insulin-in-adults-with-type-1-diabetes-by-24-week-continuous-glucose-monitoring [Accessed April 2019].
8. Peters AL et al. Diabetes Care 2015 Jun; dc150843.https://doi.org/10.2337/dc15-0843
9. Rosenstock J, Ferrannini E. Diabetes Care 2015 Sep; 38(9): 1638-1642.https://doi.org/10.2337/dc15-1380
10. Garber AJ et al. Endocrine Practice: January 2019, Vol. 25, No. 1, pp. 69-100. https://doi.org/10.4158/CS-2018-0535
11. Danne T et al. Diabetes Care 2019 Feb; dc182316.https://doi.org/10.2337/dc18-2316

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.

Sanofi, Empowering Life

Sanofi Media Relations Contact
Nicolas Kressmann
Tel: +1 (732) 532-5318
nicolas.kressmann@sanofi.com

Sanofi Investor Relations Contact
George Grofik
Tel: +33 (0)1 53 77 45 45
ir@sanofi.com

Lexicon Media Relations Contact
Chas Schultz
Tel: 281-863-3421
cschultz@lexpharma.com

Lexicon Investor Relations Contact
Kimberly Lee, D.O.
Tel: 281-863-3383
klee@lexpharma.com

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, 2018. 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, 2018, 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.