SANOFI

Press Release

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

EMA to review sotagliflozin as potential treatment for type 1 diabetes

Paris – March 29, 2018 – The European Medicines Agency (EMA) has accepted for review Sanofi's regulatory submission for sotagliflozin. If approved, the oral treatment would be used as an addition to insulin therapy to improve blood sugar control in adults with type 1 diabetes mellitus. Developed in partnership with Lexicon Pharmaceuticals, Inc., sotagliflozin is an investigational dual inhibitor of SGLT-1 and SGLT-2, proteins that influence how the intestines and kidneys process blood sugar (glucose).

> "*Despite recent advances, the challenges of type 1 diabetes management prevent many patients from reaching their treatment goals. There is a need for therapies to be used in addition to insulin to help people with type 1 diabetes better control their blood sugar. Sotagliflozin is the first SGLT-1/2 dual inhibitor to be accepted for regulatory review in Europe,*" says Jorge Insuasty, Senior-Vice President, Global Head of Development, Sanofi. "*We look forward to working with the EMA through the review process to bring this potential treatment to patients.*"

The Marketing Authorization Application submitted to EMA is based on data from the inTandem clinical trial program which consists of three Phase 3 clinical trials assessing the safety and efficacy of sotagliflozin in approximately 3,000 adults with inadequately controlled type 1 diabetes.[1–3] Its safety and efficacy have not been fully evaluated by any regulatory authority.

References

1. Buse J et al, Presentation 69-OR at American Diabetes Association 77th Scientific Sessions (ADA 2017), San Diego, CA, U.S.
2. Danne T. Presentation 185-OR at European Association for the Study of Diabetes Annual Meeting (EASD 2017), Lisbon, Portugal.
3. Garg SK, et al. N Engl J Med 2017; 377:2337-2348, DOI: 10.1056/NEJMoa1708337.

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

Media Relations Contact
Jack Cox
Tel. : +33 (0)1 53 77 46 46
mr@sanofi.com

Investor Relations Contact
George Grofik
Tel.: +33 (0)1 53 77 45 45
ir@sanofi.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 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, 2017. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.