



Sanofi and Lexicon Pharmaceuticals to Collaborate on Sotagliflozin, an Investigational New Oral Medicine for People with Diabetes

Paris and The Woodlands, TX - November 6, 2015 - [Sanofi](#) and [Lexicon Pharmaceuticals](#), Inc. (NASDAQ: [LXRX](#)) announced today that they have entered into a collaboration and license agreement for the development and commercialization of sotagliflozin, an investigational new oral dual inhibitor of sodium-glucose cotransporters 1 and 2 (SGLT-1 and SGLT-2), which could be a potential treatment option for people with diabetes.

"This agreement with Lexicon reinforces our commitment to helping people living with diabetes," said Pascale Witz, Executive Vice President, Sanofi, who will lead the Global Diabetes and Cardiovascular Care Business Unit in the company's new organizational structure. *"Adding sotagliflozin to our portfolio, which includes medicines at virtually every stage of the treatment pathway, highlights our focus on providing a large and diverse set of therapeutic options for people with this disease."*

The developmental medicine sotagliflozin (LX4211) is currently being studied in two pivotal Phase 3 trials in type 1 diabetes, which are expected to report top-line results during the second half of 2016. Phase 3 trials in type 2 diabetes are expected to begin in 2016. Sotagliflozin has previously shown encouraging results in exploratory (Phase 2) studies, including reduction of blood sugar (HbA_{1c}), improvement in glycemic variability and reduced meal-time insulin dose compared with placebo in type 1 diabetics. Phase 2 studies exploring treatment in people with type 2 diabetes, including those with renal impairment, showed lowering of blood sugar (HbA_{1c}), weight loss and blood pressure improvements. No increase in hypoglycemic events was seen with sotagliflozin compared to background therapy in the Phase 2 program. The adverse event profile in the Phase 2 program was similar to other products in this class and reflective of the urinary glucose excretion associated with sotagliflozin's inhibition of SGLT-2.

These results indicate that sotagliflozin could have the potential to become an important option among oral anti-diabetic medicines and provide a strong rationale for the further investigation of this compound as a treatment for people with diabetes.

"Lexicon firmly believes in the potential of sotagliflozin for patients living with diabetes. It has been our strategy to focus our resources on the development of sotagliflozin for type 1 diabetes and to pursue a strategic partnership with respect to type 2 diabetes only if it would strengthen stakeholder value under a fully integrated diabetes program. We believe this arrangement with Sanofi achieves that objective," said Lexicon President and Chief Executive Officer Lonnel Coats. *"Sanofi's patient-centric focus in diabetes, and its rich history of innovation in diabetes, make it an exceedingly attractive partner which is well positioned to unlock the full potential of sotagliflozin for patients living with diabetes. Also consistent with our strategy, Lexicon will continue to lead the development of sotagliflozin for type 1 diabetes and have rights to participate in the commercialization of sotagliflozin for type 1 diabetes in the United States."*

Under the terms of the agreement, Lexicon will receive an upfront payment of \$300 million and is eligible to receive development, regulatory and sales milestone payments of up to \$1.4 billion. Lexicon is also entitled to tiered, escalating double digit percentage royalties of net sales of sotagliflozin.

Sanofi obtains an exclusive worldwide license to develop, manufacture and commercialize sotagliflozin. Lexicon will continue to be responsible for all clinical development activities relating to type 1 diabetes and will retain an exclusive option to co-promote and have a significant role, in collaboration with Sanofi, in the commercialization of sotagliflozin for the treatment of type 1 diabetes in the United States. Sanofi will be responsible for all clinical development and commercialization activities of sotagliflozin for the treatment of type 2 diabetes worldwide and will be solely responsible for the commercialization of sotagliflozin for the treatment of type 1 diabetes outside the United States. Lexicon will share in the funding of a portion of the planned type 2 diabetes development costs over the next three years, up to an aggregate of \$100 million.

The agreement is subject to customary filing and review under the Hart-Scott-Rodino Antitrust Improvements Act.

The investigational agent described above is currently under clinical development and its safety and efficacy have not been evaluated by any regulatory authority.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: [SAN](#)) and in New York (NYSE: [SNY](#)).

About Lexicon

Lexicon 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 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. Lexicon has a pipeline of promising drug candidates in clinical and pre-clinical development in oncology, diabetes and metabolism. For additional information please visit www.lexpharma.com.

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, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, 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, 2014. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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