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FDA Panel recommends Sanofi's diabetes drug

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Sanofi has announced that the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the US Food and Drug Administration (FDA) recommended the approval of the New Drug Application (NDA) for the investigational fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide for the treatment of adults with type 2 diabetes.

The 15-member panel voted 12 to 2 (1 panelist did not vote due to travel) to approve the fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide.

"We are pleased by the Advisory Committee's recommendation for approval of this investigational diabetes therapy," said Dr Elias Zerhouni, president, Global R&D, Sanofi. "By combining the complementary therapeutic effects of insulin glargine on fasting plasma glucose and of lixisenatide on postprandial plasma glucose, both of which can contribute to HbA1c lowering, this fixed-ratio product may address some of the unmet needs of adults living with type 2 diabetes who are considering initiating or intensifying insulin. We look forward to continuing to work with the FDA as it completes its reviews of these New Drug Applications."

The NDA submission for the fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide is based on data from two Phase 3 studies, which enrolled more than 1,900 adults worldwide to evaluate the efficacy and safety of the fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide when used in patient populations insufficiently controlled after oral antidiabetic agents (OADs) and after basal insulin therapy, respectively. Both studies met their primary endpoints. The full results of both studies will be presented in June 2016 at the American Diabetes Association's 76th Scientific Sessions.

The NDA submission for lixisenatide is based on results from the GetGoal clinical program, which included 13 clinical trials involving more than 5,000 adults with type 2 diabetes. The NDA submission for lixisenatide also includes findings from the

ELIXA study, a long-term cardiovascular (CV) outcomes study in adults with type 2 diabetes and high CV risk (i.e., patients who have recently experienced a spontaneous acute coronary syndrome event).

Lixisenatide and the fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide are undergoing FDA review, with decisions anticipated in July and August 2016, respectively. The proprietary names for both compounds in the U.S. are under consideration. Lixisenatide is currently approved in more than 60 countries worldwide under the proprietary name Lyxumia. The fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide was submitted for regulatory review in the European Union in March 2016 and has not yet been approved for use by any health authority.