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# FDA accepts sanofi's NDA

22 February 2016 | News | By BioSpectrum Bureau

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Sanofi announced that the US Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for its 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.

Following the redemption of a Priority Review Voucher with the submission, an FDA decision is anticipated in August 2016.

"The FDA filing notification is an important milestone for Sanofi as we work to broaden our diabetes portfolio," said Ms Pascale Witz, Executive Vice President, Global Diabetes & Cardiovascular, Sanofi. "Physicians may need to consider fasting and mealtime blood glucose imbalances in their overall management of diabetes, and additional treatment options are needed. We look forward to working with the FDA during the review process with a view toward bringing this investigational medicine to adults with type 2 diabetes in the US"

This NDA submission is based on data from two Phase 3 studies, which enrolled more than 1,900 patients worldwide to evaluate the safety and efficacy of the fixed-ratio combination when used in patient populations insufficiently controlled after oral antidiabetic agents (OADs) and after basal insulin therapy, respectively.

Both studies met their primary endpoints and will be presented at a medical congress in 2016.

The safety and efficacy of the fixed-ratio combination have not been evaluated by any regulatory authority, and the proprietary name is under consideration.

Preparations are on track for regulatory submission in the European Union in March 2016.

The investigational GLP-1 receptor agonist lixisenatide was evaluated in patients with type 2 diabetes and is also currently under review by the FDA.

The NDA for lixisenatide was accepted in September 2015, and an FDA decision is anticipated in July 2016.