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Sanofi seeks approval for Lyxumia in Japan

11 June 2012 | Regulatory | By BioSpectrum Bureau

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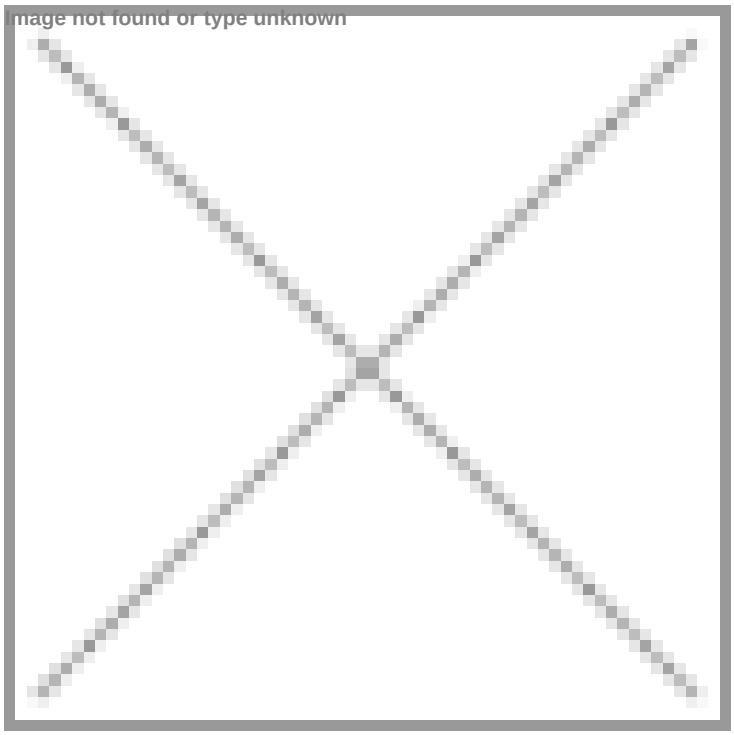

Singapore: Sanofi has submitted the marketing authorization application for Lyxumia, (lixisenatide), an investigational once-daily GLP-1 receptor agonist, to the Ministry of Health, Labour and Welfare in Japan.

The application is supported by data from the extensive international GetGoal phase III clinical trial program, which has assessed lixisenatide's intended indication for the treatment of adults with type 2 diabetes with the aim of achieving glycemic control in patients who were not adequately controlled on
diet & exercise with or without oral anti-diabetics and/or basal insulin. The GetGoal program has enrolled more than 5,000 participants, including subjects in Japan, and has studied the highest numbers of patients to evaluate a GLP-1 in combination with basal insulin 1.

The GetGoal program has established lixisenatide's good efficacy and safety profile, demonstrating a significant reduction in HbA1c. As expected from a GLP-1 receptor agonist, lixisenatide was associated with a low risk of hypoglycemia, and in terms of tolerability, nausea and vomiting were the most commonly reported adverse events.

The European Medicine Agency acknowledged the receipt of the market authorization application filing for lixisenatide in November 2011. Submission for regulatory approval of lixisenatide in the US is expected in Q4 2012.