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Sanofi withdraws diabetes drug NDA in the US

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Singapore: Global pharmaceutical company, Sanofi has temporarily withdrawn new drug application (NDA) for lixisenatide in the US and plans to resubmit in 2015.

Lixisenatide is approved in Europe for the treatment of adults with type 2 diabetes mellitus to achieve glycemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycemic control.

The decision to withdraw the lixisenatide application follows discussions with the US FDA regarding its proposed process for the review of interim data. Sanofi believes that potential public disclosure of early interim data, even with safeguards, could potentially compromise the integrity of the ongoing Elixa study. Sanofi's decision is not related to safety issues or deficiencies in the NDA.

The Elixa study continues as planned and is fully enrolled. Complete results should be available in approximately 15 months. Therefore, Sanofi came to the conclusion that the most appropriate option is to support the FDA's evaluation of lixisenatide based on the complete results of the Elixa study rather than interim data.

The combination of lixisenatide and Lantus (basal insulin), the investigational LixiLan fixed-ratio product, remains on schedule to enter into phase III in the first half of 2014.