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Physician Views: Sanofi's successor to Lantus - are endocrinologists impressed?

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Abstracts

Accounting for approximately 22 percent of Sanofi's branded pharmaceutical revenue – and still positioned as one of the industry's most prominent growth drivers – its long-acting basal insulin Lantus is widely considered to be the company's most important product franchise.

Similarly, an 'enhanced' version of Lantus, which is designed to reduce cases of severe and nocturnal hypoglycaemia – currently known as Insulin U300 – is the most important product in Sanofi's late-stage R&D pipeline.

With submission to regulators expected next year, the passage of U300 towards market will play a pivotal role in allowing Sanofi to retain – and potentially expand – its leadership of the US long-acting basal insulin market.

Lantus currently commands an approximate 72 percent share of the US market, which effectively acts as a duopoly (Novo Nordisk's Levemir accounts for an approximate 19 percent share). A new competitive threat in the form of Novo Nordisk's Tresiba had been expected this year, but the FDA chose not to approve the product until an outcomes study is completed – pushing a potential launch back until 2017 - see In Focus: FDA rejection of Tresiba – unexpected, unnecessary and avoidable? – How a delayed US launch for Novo Nordisk's blockbuster in waiting continues to shape the diabetes market.

Like U300, Tresiba is designed to offer an improved profile versus Lantus, primarily via a superior nocturnal hypoglycaemia benefit. With Tresiba's launch delayed for a number of years in the US – it has been launched in selected European markets and Japan – there appears to be an opportunity for Sanofi to push home an advantage with U300,

particularly by building on the entrenchment of its Lantus franchise.

Sanofi has released numerous Phase III data for U300, the most recent last week to mixed analyst reaction.

Having previously demonstrated a statistically significant reduction in the number of severe or confirmed cases of nocturnal hypoglycaemia among high-risk patients (those who have failed to control their blood glucose levels via treatment with basal insulin and oral medication), reduction in treatment-naive patients was notably lower and only trended towards statistical significance.

This prompted a number of analysts to suggest last week that use of U300 may ultimately be curtailed among a broader proportion of insulin-eligible patients. Although the Phase III data for U300 and Tresiba are not directly comparable, most analysts suggest that Novo Nordisk's product appears to be better at reducing hypoglycaemic events. Nevertheless, new data for U300 enhances its approvability and will allow Sanofi to build on the dominant position it already commands in the long-acting basal insulin market.

To better understand how U300 may be received and used (assuming approval is secured), FirstWord is polling US-based endocrinologists to gauge their reaction to the Phase III data for Sanofi's product. The poll will specifically ask endocrinologists to provide.

Their assessment of U300 Phase III data in insulin-naive patients

Their assessment of U300 Phase III data in patients failing to control blood glucose levels with insulin and oral therapy

Their assessment of U300 Phase III data in patients being treated with basal and mealtime insulin

Their anticipated usage of U300 in patients failing to control blood glucose levels with insulin and oral therapy

Their anticipated usage of U300 in insulin-naive patients

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