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Novo Nordisk 'Caught Short' By Lantus Exclusion

by Sukaina Virji

Novo Nordisk says it was caught by surprise when US pharmacy benefit managers decided to exclude Sanofi's basal insulin Lantus and downgrade its own Levemir from formularies in favor of Eli Lilly's soon-to-be launched biosimilar Basaglar. Novo had been hoping for more time to secure some of Lantus' US market share with its new diabetes product Tresiba, but now accepts that will not happen.

The diabetes market has been an area of significant pushback from payers and greater demands for rebates, putting pressure on sales. *Novo Nordisk AS* has been one of the most significant casualties, and cut its growth forecast for 2017 last month. (Also see "*Novo Nordisk Shakes Up R&D Strategy To Cope With US Pricing Pressures*" - Scrip, 28 Oct, 2016.)

"People have said, 'but you knew the biosimilar was coming,'" said Novo Nordisk's IR manager Melanie Raouzeos at the Jefferies Healthcare conference in London on Nov. 16-17. "We did know it was coming, but we didn't expect that the PBMs would be so aggressive about accepting it. We thought it would be launched and then take its time to be accepted."

Novo Nordisk's basal insulin *Levemir* (insulin detemir) has always lagged behind *Sanofi*'s *Lantus* (insulin glargine) in sales ($2.68bn in 2015 versus Lantus' $6.98bn), likely because of its comparatively late market entry.

With Lantus going off patent, both companies developed new drugs to shore up their diabetes franchises. Sanofi's

Sanofi/Novo Nordisk In Head-To-Head Diabetes Combo Approvals

By Sukaina Virji

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Sanofi and Novo Nordisk – which are battling to shore up their diabetes franchises in the

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Toujeo (insulin degludec) was approved by FDA in February 2015 and Novo Nordisk's *Tresiba* (insulin glargine) in September 2015. However, these have arguably modest benefits over their predecessors.

"Tresiba has had good market access, but we were forced to give higher rebates [than planned]. Biosimilar Lantus left us with no choice," said Raouzeos. Tresiba has been taking market share from Lantus and "cannibalizing Levemir," she added.

face of biosimilar competition – have simultaneously garnered US approval for new combination products to treat the disease. However, analysts expect the two companies to adopt different pricing strategies.

Read the full article here

Semaglutide Promise

Novo Nordisk has said previously it plans to file its *Victoza* (liraglutide) follow-on product, semaglutide, in the US by the end of 2016.

Raouzeos noted that semaglutide was recently the second GLP-1 agonist to show positive results in a major cardiovascular outcomes trial (CVOT) in type 2 patients at high risk of CV disease. In the SUSTAIN-6 trial, semaglutide demonstrated a 26% risk reduction compared with placebo.

Victoza demonstrated CV benefit in the LEADER trial earlier this year.

The SGLT2 inhibitor empagliflozin (*Jardiance*, *Boehringer Ingelheim GMBH*/*Eli Lilly & Co.*) was the first to show a reduction in CV death in the EMPA-REG trial.

Another Threat

Aside from diabetes, Novo Nordisk's hemophilia business faces a significant threat.

Competition is expected shortly in the form of *Roche*'s late-stage promising bispecific antibody for hemophilia A, emicizumab (ACE910), which is being touted as a future blockbuster. Emicizumab, given once-weekly subcutaneously, has demonstrated prophylactic efficacy for people with severe hemophilia A, regardless of the presence of Factor VIII inhibitor antibodies (which develop in around 30%

Diabetes Treatment Shift Coming? Cleveland Clinic's Nissen Declares Victory

By Cole Werble

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A 'complete shift' in diabetes prescribing practices toward cardiovascular protective agents is occurring more slowly than anticipated, but Cleveland Clinic Cardiology chief Steve Nissen is ready to claim success in decade-long effort to shift diabetes drug

of hemophilia A patients), potentially streamlining treatment of this condition.

Currently, patients who develop inhibitor antibodies are treated with bypass agents such as Novo Nordisk's *NovoSeven* and *Shire PLC*'s *Feiba*.

treatment focus from blood sugar to cardiovascular mortality.

Read the full article here

If approved, "50% of NovoSeven's sales are at risk," said Novo Nordisk's Raouzeos. Sales in 2015 were around $1.5bn.

However, despite $3bn in cash on its balance sheet and no debt, Novo Nordisk will not be adding "new legs" to its business, said Raouzeos. "In terms of business development, we're interested in add-ons or adjacent activity, but all M&A will be modest."