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Physician Views: What opportunity for biosimilar basal insulin?

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Abstracts

Two weeks ago, Sanofi significantly downgraded internal revenue projections for Lantus, its long-acting basal insulin treatment, which generated annual sales of $7.6 billion in 2013. The company no longer anticipates growth for the franchise in the US market next year, as a result of having to offer more aggressive rebates to secure formulary positioning.

Suggestions that aggressive price increases for Lantus have caught up with Sanofi in the US payer environment come as the basal insulin market is nearing an important juncture. A number of new basal products are expected to launch in the next few years, including Novo Nordisk's Tresiba, Eli Lilly's Peglispro and Sanofi's own Toujeo. The first biosimilar/generic version of Lantus, co-developed by Eli Lilly and Boehringer Ingelheim, is also expected to launch in Europe in H1 2015 (Spotlight On: Something else for Sanofi to consider – what threat from biosimilar Lantus?).

With new branded products deemed by many analysts to offer only modest advantages over available therapies, increased competition in the segment could provide more ammunition for payers who have historically had minimal opportunity to leverage discounts from an oligopolistic market where net price increases and marginal rebating have been the norm.

Eli Lilly's insulin glargine product is widely expected to launch in the US during 2016, with investors and analysts told by management that the franchise will be treated as a new 'brand.' This has been heavily influenced by the fact that at this stage Eli Lilly has not been awarded interchangeability in the US, whereby Lantus could be switched automatically for its product at the pharmacy.

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Some analysts have pointed out, however, that Eli Lilly will be required to offer a notable discount to secure market share gain for its insulin glargine franchise. How this strategy plays out while Eli Lilly simultaneously tries to bring branded Peglispro insulin to market remains to be seen.

A second developer of biosimilar/generic Lantus, Mylan, is further from the market but is currently in discussion with the FDA regarding the design of pivotal-stage studies and necessary regulatory route to support approval of a substitutable product.

Critically, Mylan has no presence in the branded basal insulin market, allowing it to compete more aggressively with incumbents (both in terms of pursuing substitutability or potentially on price). On the flipside, with this space dominated by a small number of well established players, it remains to be seen how comfortable physicians would be using a 'biosimilar' insulin developed by a company with little experience in this segment.

While Sanofi has some breathing space in the US, the company recently confirmed that its 2015 full-year guidance assumes launch of Eli Lilly's biosimilar Lantus product in the EU at some stage next year. With the role of interchangeability – or automatic substitution as it is known in the region – less pronounced in the EU, pricing dynamics are likely to play a more singular role in driving uptake of Lilly's product.

Poll Questions

In light of these dynamics, FirstWord is this week polling US and EU5-based endocrinologists with the following 5 questions...

> How comfortable would you be prescribing a biosimilar/generic version of Lantus (insulin glargine)?
>
> Would your comfort levels rise if this product had been developed, manufactured and marketed by a company with a strong existing presence in the insulin market?
>
> BIn a real-world setting, what percentage discount do you think will be necessary to drive significant uptake of the first available biosimilar/generic Lantus (insulin glargine) product?
>
> And if the product was priced at this level, what percentage of patients newly

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eligible for treatment with a basal insulin would you expect to be treating with the biosimilar/generic version 12 months after launch? (US respondents consider the biosimilar/generic as not being specifically approved as 'interchangeable' with branded Lantus).

Similarly, what percentage of patients would you be comfortable switching from branded Lantus/Levemir to the biosimilar/generic version 12 months after launch? (US respondents consider the biosimilar/generic as not being specifically approved as 'interchangeable' with branded Lantus)

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