

Physician Views: A post-AdCom assessment of Novo Nordisk's liraglutide for obesity

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Abstracts

Novo Nordisk took an important step in its bid to enter the obesity market last week, when an FDA Advisory Committee voted 14-1 in favour to approve a 3mg version of its diabetes treatment liraglutide for this indication.

This outcome reflects validation of the efficacy profile demonstrated by liraglutide in obesity, noted analysts, but importantly also showed that there was minimal concern about its side-effect profile. Indeed, analysts at JP Morgan described the FDA presentation as 'benign,' and stated that there is an increased likelihood that approval will occur on or before October 20.

A few side-effect concerns linger, but post-AdCom consensus suggests these will act to shape how the product is utilised by physicians, rather than dictate whether it gains approval. The commercial opportunity for liraglutide – which will be sold under the brand name Saxenda – is one that is still open to some debate. For example, beyond the clinical profile of liraglutide as an obesity therapy, will uptake be limited due to the drug's cost and injectable administration, argue bearish analysts.

Novo Nordisk hopes that Saxenda proves to be predictive of a longer-term success in the obesity market, which will centre around the development of new therapies designed to target the underlying mechanics of the condition – see Spotlight On: Exit from inflammatory development a case of time management, explains Novo Nordisk's chief science officer to FirstWord.

The commercial opportunity for Saxenda may hang on a more straightforward rationale, however, and depend on how many existing diabetes patients treated with liraglutide 1.8mg (as Victoza) who are also morbidly obese can be 'up-scaled' with treatment to the



3mg version – which could sell for around 3 times the price of Victoza based on a consensus of analyst estimates (and taking into account comments about pricing from Novo management).

Reflecting a key component of Novo Nordisk's obesity strategy – which is to target physicians they are familiar with and whom are familiar with the company's products – severely obese pre-diabetic patients and those suffering with obesity and other co-morbidities will initially be targeted to use Saxenda.

With these factors in mind – and given last week's positive AdCom vote – FirstWord is polling US-based endocrinologists and general practitioners on their anticipated usage of Saxenda, assuming that approval is secured. Specifically we are asking them.

To what percentage of obese diabetics (BMI>40) – already receiving treatment with a GLP-1 agonist – they would expect to prescribe the higher 3mg dose of liraglutide if approved for obesity

Whether approval of liraglutide 3mg for obesity would encourage them to switch more diabetics (not being treated with a GLP-1 agonist) to treatment with Victoza (on account of approval further validating liraglutide's weight-loss profile)

To what percentage of morbidly obese patients with pre-diabetes they would anticipate prescribing 3mg liraglutide

To what percentage of morbidly obese patients with other co-morbidities they would anticipate prescribing 3mg liraglutide

What factors will act as significant barriers to their potential usage of 3mg liraglutide for the treatment of obesity



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