

MEMORANDUM

Novo Nordisk launches Levemir FlexTouch pen in the US - June 23, 2014

Executive Highlights

- The FlexTouch pen is the only pre-filled insulin pen with a push-button that does not telescope out when patients dial up the dose, improving ease of use.
- According to Novo Nordisk, US commercial coverage for the FlexTouch is slightly greater than that for Sanofi's Lantus SoloSTAR.

Novo Nordisk recently <u>announced</u> the US launch of the FlexTouch pen for the basal insulin Levemir (insulin detemir); this was featured prominently at Novo Nordisk's booth at ADA (read our <u>coverage</u>). The FlexTouch is currently the only prefilled insulin pen with a push-button that does not telescope out when the dosage is dialed up - "Because we can't redesign thumbs," displays at ADA said, "we designed the FlexTouch." The pen also raises the maximum dose to 80 units from 60 units and provides an easily perceptible click at the end of dosing (we think many patients feel this is satisfying to hear, given what a dangerous drug insulin is - just the extra certainty that the dose has been delivered is a positive). It is slightly larger than its predecessor, the FlexPen. The FlexTouch is available on more than 96% of commercial and Medicare Part D plans nationwide, and Novo Nordisk's ADA display highlighted that the pen's coverage is slightly better than that for Sanofi's flagship Lantus (insulin glargine) SoloSTAR pen.

Novo Nordisk's FlexTouch was approved in Europe back in July 2011, and has launched in several countries, including Denmark, the UK, Canada, and Japan. It was approved in the US in November 2013, so has taken a bit of time to launch. Levemir has been one of Novo Nordisk's best-performing products in recent quarters (up 21% year-over-year in 1Q14; see our Novo Nordisk 1Q14 Report) and we would quess the delivery of Levemir through a better pen certainly won't hurt. We suspect the revenue boost for Levemir is perhaps be due to the extra marketing budget that was originally allocated for the ultra-long-acting basal insulin Tresiba (insulin degludec), which received an FDA Complete Response Letter last year and is delayed significantly as a result (read our report on what the CRL means for diabetes drug development). We continue to question whether cardiovascular outcomes trials should be required for so many drugs, preapproval, degludec being among the most egregious examples of unnecessary delays in our view, particularly given the option of a conditional approval or an approval in some patients that would have enabled some experience with degludec to begin as well as ongoing development for iDegLira (this can't be submitted to the FDA in the US until degludec is approved). All this said, degludec is a bit ahead of the original very delayed post CRL schedule (see our Novo Nordisk 1Q14 Report for more on that timeline update). As to what basal insulin will come out ahead and win or steal market share, we point out device design is particularly key to the patient experience with a drug. Lantus has been the winner over Levemir for a number of years; that said, we believe that the features of the FlexTouch will have appeal for many type 2 diabetes patients, especially the frail or elderly. Even more important, of course, is access particularly in single-payer systems but also in the increasingly competitive US.

-- by Manu Venkat and Kelly Close

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