CLOSER LOOK

MEMORANDUM

Novo Nordisk resubmits faster-acting insulin aspart to FDA, following Complete Response Letter in October - March 29, 2017

Novo Nordisk announced today that faster-acting insulin aspart has been re-submitted to the FDA. The product launched in Canada, its first market, earlier this week under the brand name Fiasp and received marketing authorization from the EMA in January. A US regulatory decision is now expected in 4Q17, according to the company's announcement. This is the second time Novo Nordisk has submitted a New Drug Application (NDA) for the next-generation prandial insulin - the first was met with a Complete Response Letter (CRL) in October. This news follows timing outlined during Novo Nordisk's 4Q16 update in early February, when management shared that faster-acting aspart would be resubmitted within three months (we're happy to see the revised NDA turned in even sooner than expected, which we hope and expect will help the company reach its target of an approval by end of year). The CRL cited concerns with the immunogenicity and pharmacology assay for the faster-acting insulin, and we'd be curious to see what additional data Novo Nordisk gathered to address this. We're thrilled to see the company carry forward this first-to-market next-gen mealtime insulin therapy - faster onset and offset could make bolusing easier and less error-prone, could reduce hypoglycemia risk, and could be particularly promising in pumps. True, some have interpreted the phase 3 Onset 1, 2, and 3 results to show incremental rather than disruptive benefit for faster-acting aspart vs. NovoLog (insulin aspart), but we'll take incremental improvement any day when it could so meaningfully improve quality of life for patients. What we have isn't that great, so we're excited for any progress. We have our fingers crossed for a swift FDA approval this time around, and for pricing not too much more expensive with NovoLog if/when the product is approved for the US market. Faster-acting insulin aspart was also recently approved in Norway and Iceland; it is under review in Switzerland, Australia, Brazil, South Africa, Argentina, and Israel.

-- by Payal Marathe, Helen Gao, and Kelly Close