23rd May 2016

Healthcare

Novo Nordisk

Price DKK359.10

How much semantic is the discussion recommended on Xultophy?

Fair Value DKK400 (+11%) **NEUTRAL**

Bloomberg	NOVOB DC
Reuters	NOVOB.CO
12-month High / Low (DKK)	410.7 / 306.4
Market Cap (DKKm)	722,712
Avg. 6m daily volume (000)	2 581

	1 M	3 M	6 M	31/12/15
Absolute perf.	-3.6%	5.6%	-6.3%	-10.2%
Healthcare	-2.0%	2.7%	-11.3%	-9.6%
DJ Stoxx 600	-3.6%	3.6%	-11.5%	-7.6%

	2015	2016e	2017e	2018e
P/E	26.5x	23.9x	21.7x	20.5x
Div yield (%)	1.8%	1.9%	2.1%	2.2%

ANALYSIS

- 48 hours ahead of any FDA AdCom, briefing documents are posted on the FDA's website and this was the case for Xultophy last Friday as experts are due to meet tomorrow to discuss Novo's application for the fixed-dose combination of liraglutide and degludec.
- At first glance, and as is often the case, the documents posted point our weaknesses in the clinical data package submitted to the regulator. In particular, they point out what they call bias in clinical studies aimed at comparing IdegLira to the single component basal insulin degludec (Tresiba). Novo Nordisk disagrees with the statement and states that it demonstrated superiority against each of the two components of the combination. The FDA actually notes that the 26-week comparator HbA1c does not reflect a period of preceding glycemic stability and so concludes that "due to trial design concerns, [it is] not able to conclude that IdegLira is superior to IDeg".
- It is true that Novo Nordisk spent more time comparing the combination to standard basal insulin Lantus than to its own basal insulin Tresiba, because this makes more sense from a marketing standpoint. What the agency looks uncomfortable with is the concept of combining fixed doses of the two drugs whereas basal insulin usually requires careful up-titration. One of the questions to the panellists is precisely this one. It is not ideal and Sanofi tried and failed to make a fix-flex pen device but after all pre-mixed insulins already use fixed doses of insulins!
- But the central question in our view, as anticipated, is very much the one of the positioning of the drug as the first two questions relate to who should receive such a treatment i.e. naïve patients or patients having previously failed on any of the two components.

VALUATION

- We do not expect the experts to fully follow the FDA in its cautious approach to the concept of basal/GLP1 FDC. Approval should not be an issue in our view and we do not expect any need for an extra clinical trial before getting the green light.
- That said, we expect the label could restrict use to resistant patients but this is very much how both Novo-Nordisk and Sanofi presented the opportunity of their respective drugs i.e. as an "efficacious alternative to insulin intensification" as stated by Novo at its CMD 2015.

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