

Sector View

Pharmaceuticals

IdegLira and IGlarLixi both get strong support from AdCom's panel voters

	1 M	3 M	6 M	31/12/15
Healthcare	-0.3%	5.8%	-7.6%	-7.7%
DJ Stoxx 600	-1.2%	7.5%	-8.4%	-5.9%

*Stoxx Sector Indices

Companies covered

ACTELION	BUY	CHF173
ASTRAZENECA	BUY	5100p
BAYER	NEUTRAL	U.R.
GLAXOSMITHKLINE	BUY	1700p
IPSEN	BUY	EUR63
NOVARTIS	NEUTRAL	CHF89
NOVO NORDISK	NEUTRAL	DKK400
ROCHE HOLDING	BUY	CHF293
SANOFI	NEUTRAL	EUR86
SHIRE PLC	BUY	5900p
UCB	NEUTRAL	EUR80

After backing Xultophy by an unanimous vote 16-0 in favour of its approval, FDA AdCom's vote yesterday also supported strongly the approval of Sanofi/Zealand's fixed-combination of glargine and lixisenatide (12-2). This is very much in line with expectations. Now the toughest part of the process is starting, with discussions on labelling, positioning, reimbursement and pricing. The products are key for all three players involved.

ANALYSIS

- For Novo-Nordisk, Sanofi and Zealand now, the first regulatory step for their fixed-dose combinations of basal insulin and GLP1 is behind them and panellists have strongly supported the approval of their respective products. The approval per se is not a surprise but the magnitude of the support is reassuring. So, it is now highly likely that the two products will be approved by the FDA in coming months.
- That said, the story is far from over because although we've seen meaningful delays in approving drugs for diabetes in the past (from Tresiba to Lyxumia or Saxa-dapa), and although approvals are not yet fully granted, for some time the heart of the topic in our view is elsewhere i.e. in the final labelling including positioning (initiation or intensification), in the reimbursement and pricing. We think we are clearly in a situation where, in the current environment, payers will try to limit the influence of these drugs while their sponsors will try to make them fully new and ultimately the best available products in a single injection and with single co-pay.
- We are in particular very interested in seeing how Novo-Nordisk and Sanofi will exactly position their respective drugs. Our understanding from recent discussions is that LixiLan is no longer a brand name considered for Sanofi that would like to give it full virginity and make it a completely different proposition from Lantus. At the same time, the objective is to switch as many non-controlled Lantus patients as possible from Lantus to the FDC before biosimilars get too influential. From a pricing standpoint also we have heard very different strategies between Sanofi and Novo-Nordisk and we are curious to see how it will play out and influence payers. IGlarLixi offers leverage to Sanofi's franchise and will get (small) premium over Lantus whereas it is less easy for Novo-Nordisk to get a premium over Victoza although it has to be the case.

VALUATION

- No change to our numbers for the time being. However, keep in mind that we have IGlarLixi is Zealand's FV with a PoS of 85%. An extra 5% PoS would add DKK6 to the FV.

NEXT CATALYSTS

- 10-14th June 2016: ADA meeting, New Orleans (full phase III data for IGlarLixi presented)

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Distribution of stock ratings

BUY ratings 72%

NEUTRAL ratings 0%

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