6th April 2016

Healthcare

AstraZeneca

Price 3,951p

Saxagliptin-containing products to carry new warning for HF

Fair Value 5360p vs. 5520p (+36%) **BUY**

Bloomberg	AZN LN
Reuters	AZN.L
12-month High / Low (p)	4,863 / 3,890
Market Cap (GBPm)	49,960
Avg. 6m daily volume (000)	2 515

	1 M	3 M	6 M	31/12/15
Absolute perf.	-1.7%	-13.4%	-7.0%	-14.4%
Healthcare	-2.0%	-12.4%	-10.1%	-12.7%
DJ Stoxx 600	-4.0%	-8.6%	-8.4%	-10.3%

	2015	2016e	2017e	2018e
P/E	13.1x	14.2x	14.6x	13.6x
Div yield (%)	5.0%	5.0%	5.0%	5.0%

ANALYSIS

- Although it took the FDA some time, the agency has decided to act and ask for a label change with a new warning being added to saxagliptin and alogliptin-based products to highlight the increased risk of heart failure associated with the use of these drugs. This follows a review of various clinical trial results, including SAVOR phase III trial that, back in 2014 raised questions about a potential risk of increase in hospitalisations associated with heart failure (HF). In April 2015, an Advisory Committee (EMDAC) met and voted 13 to 1 that saxagliptin had an acceptable safety profile while 14 out of 15 members asked for a new safety mention on the label. It took a year to be formally required by the FDA.
- As such, the move is no real surprise. That said, what makes it particularly negative for AstraZeneca is that saxagliptin and alogliptin are the only two DPP-IV inhibitors to be asked to carry this new warning, which introduces a clearly negative differentiating factor between these two drugs and their competitors namely first-in-class alogliptin (Merck) and Lilly's linagliptin.
- AstraZeneca was already in trouble with Onglyza in the US and was facing tough competition, so much so that it said during 2015 that the drug would be de-prioritised in favour of Forxiga. However, first SGLT-2 inhibitors are also currently under attack and we would not rule out another set of warnings for the class soon; second, if Onglyza's estimates have been sharply cut already, the FDC saxa-dapa which was resubmitted recently and is expected to be approved in H2, will carry the same warning that is very likely to limit US sales vs competition.

VALUATION

- This is unfortunately only a confirmation that Diabetes remains a tough area for AstraZeneca in the US. It is still unclear whether the company will try to adapt (including with use of BD) or walk away and reallocate priorities and resources elsewhere.
- We had already adjusted our estimates to these tough market conditions. Today's adjustment to our FV has nothing to do with the news but only refers to the change in BG's metrics for valuation methodology i.e. a new risk-free rate of 1.6% (vs. 2%) and ERP of 7% (vs. 6.4%).

NEXT CATALYSTS

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