

28th July 2016

Healthcare

**Zealand**

Price DKK119.00

**Lixisenatide approved as Adlyxin in the US**

**Fair Value DKK176 (+48%)**

**BUY**

Bloomberg	ZEAL DC
Reuters	222.F
12-month High / Low (DKK)	168.5 / 92.5
Market Cap (DKKm)	2,920
Avg. 6m daily volume (000)	114.1

	1 M	3 M	6 M	31/12/15
Absolute perf.	6.3%	-8.5%	-6.7%	-21.5%
Healthcare	9.3%	6.0%	2.5%	-3.0%
DJ Stoxx 600	11.0%	-1.6%	0.7%	-6.3%

	2015	2016e	2017e	2018e
P/E	NS	NS	NS	8.3x
Div yield (%)	NM	NM	NM	NM

#### ANALYSIS

- One significant step is now behind for Zealand as FDA approved lixisenatide in monotherapy under the brand name Adlyxin.
- The big step is the next one i.e. assessment by the US agency of fixed-dose combination of lixisenatide with basal insulin glargine (iGlarLixi), because that's where Sanofi can be differentiated in the market place and use its long history and experience with Lantus and work together with Novo-Nordisk to create a new market insulin in the field of diabetes. However, we raised concerns after the Advisory Committee that took place in May because of allergic reactions with lixisenatide and more importantly serious antibody drug formation whose level impacted the efficacy of the drug. Actually, the two observations are reproduced within the warning section of the prescribing information under "anaphylaxis and serious hypersensitivity reactions" and "immunogenicity" chapters, but with no black box around. So we do not expect these mentions in the P.I. to impact meaningfully the commercial and marketing activities deployed by Sanofi in support of the drug. As a reminder, class leader Victoza does not carry similar warnings, but has different ones and also a mention of increased risk of thyroid c-cell tumors under a black box section.

#### VALUATION

- In summary, the news is great for Sanofi and Zealand. From a valuation standpoint, because Lyxumia is already approved in Europe and Japan, we have a 100% PoS and we are not making any change to our numbers. But it is good for the confidence in iGlarLixi to be approved too although other questions are raised, notably around the pen device.

#### NEXT CATALYSTS

- End of August: PDUFA date for iGlarLixi

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## Distribution of stock ratings

BUY ratings 72%

NEUTRAL ratings 0%

SELL ratings 28%

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