

Pharmaceuticals - Diabetes

Alert: Ph III Peglispro data – strong apparent efficacy but safety signals can't be ignored

Bottom – line: threat to Novo and Sanofi still looks benign – headline Ph III data for Lilly's basal insulin Peglispro (BIL) looks optically strong from an efficacy point of view, but the safety signals we were concerned about from Ph II continue to be an issue (raised triglycerides, liver toxicity, and in today's release an increase in liver fat). Consequently, we maintain modest expectations for BIL (2020 risk-adjusted sales \$0.7bn), and see limited read-across for Sanofi's *Lantus* (2020 sales \$12bn), plus Novo's *Tresiba* and *Levemir* (2020 sales \$3bn and \$2bn).

What's new? - Lilly released top line Ph III data from 3 trials (IMAGINE-2, -4, -5) in insulin naïve Type 2 diabetics, as part of a basal-bolus regimen, and in patients already taking basal-insulin. All three trials compared BIL versus Sanofi's *Lantus*. Further Ph III data will be released ahead of US/EU regulatory filings end-1Q15, with data presentation at ADA in 2015.

Efficacy looks good (A1c, hypos, weight)... The primary endpoint of non-inferior reduction in HbA1c, versus *Lantus*, was met with BIL going on to show a statistically superior reduction in HbA1c. In all three clinical trials, BIL patients experienced statistically significant lower rates of nocturnal hypoglycemia and had "comparable to statistically significant less weight gain". We await to see whether the statistically significant differences are clinically relevant (i.e. is hypo reduction >30%) and/or whether trial design (timing of dose, definition of hypos, titration schedule) can explain the apparent differences versus *Lantus*.

...but safety signals concerning (raised TGs, liver enzymes and liver fat, lower HDL) – "small but statistically significant increases in triglycerides" were seen across all three trials. In IMAGINE-4 and IMAGINE-5, there was a corresponding small but statistically significant reduction in HDL (good cholesterol). In IMAGINE-2 and IMAGINE-4, changes in LDL (bad cholesterol) were not significantly different between BIL and *Lantus* (significantly decreased versus *Lantus* in IMAGINE-5). In an analysis across clinical trials completed to date, the rates of adverse cardiovascular events among patients taking BIL and those taking insulin glargine were similar, with the upper limit of the 95 percent confidence interval below 1.8. An increase in liver enzymes (signal for liver damage) was seen across all three trials. While no cases of severe drug-induced liver injury (Hy's Law) occurred in these studies, the market is likely to be concerned about whether this plays out in ongoing Ph III studies and, if approved, in a larger patient population. With respect to liver fat in IMAGINE-2 (insulin-naïve patients) liver fat remained unchanged versus baseline, with *Lantus* demonstrating a decrease. In IMAGINE-5, patients taking BIL experienced an increase in liver fat from baseline that stabilised after 26 weeks (unchanged for *Lantus*).

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Figure 1. Valuation

Company	RIC	Analyst	Currency	Current price	Market cap (\$bn)	Rating/Risk	Target			2015E multiple		2015-20E CAGR		2015E div yield
							Price	% upside	ETR	PE	EV/EBITDA	Sales	EPS	
US Large Cap Pharma														
AbbVie	ABBV.N	Not Rated	USD	52.3	83.1	Not Rated	NR	NR	NR	13.5	9.9	NA	NA	3.4%
Bristol Myers	BMYY.N	Andrew S Baum	USD	51.2	84.8	Buy	60.0	17%	20%	29.3	21.5	11.2%	26.7%	2.9%
Eli Lilly	LLY.N	Andrew S Baum	USD	59.4	66.5	Buy	60.0	1%	4%	18.1	9.6	5.6%	14.6%	3.3%
Johnson&Johnson	JNJ.N	Matthew J Dodds	USD	100.9	285.5	Buy	117.0	16%	18%	15.6	9.6	NA	NA	2.9%
Merck	MRK.N	Andrew S Baum	USD	55.2	161.3	Neutral	44.0	-20%	-17%	15.9	10.5	2.4%	6.8%	3.2%
Pfizer	PFE.N	Andrew S Baum	USD	29.0	185.1	Buy	36.0	24%	27%	11.6	7.5	1.6%	6.4%	3.8%
US Large-cap Pharma (mkt-cap wt avg)										16.1	10.5	4.0%	11.1%	3.2%
European Large Cap Pharma														
AstraZeneca	AZN.L	Andrew S Baum	GBP	46.2	98.3	Buy	49.0	6%	10%	18.0	11.4	4.0%	10.5%	3.7%
Bayer	BAYGN.DE	Andrew S Baum	EUR	102.3	116.4	Buy	110.0	8%	9%	13.9	10.2	4.9%	8.8%	2.7%
Novo-Nordisk	NOVOB.CO	Peter Verdult, CFA	DKK	234.5	114.1	Buy	280.0	19%	21%	20.6	15.2	9.7%	15.8%	2.3%
Roche	ROG.VX	Andrew S Baum	CHF	255.9	248.8	Buy	300.0	17%	20%	15.1	10.6	7.2%	11.8%	3.7%
Sanofi	SASY.PA	Peter Verdult, CFA	EUR	76.6	139.7	Neutral	80.0	5%	8%	13.2	9.7	3.7%	8.1%	4.2%
EU Large-cap Pharma (mkt-cap wt avg)										10.4	7.4	4.0%	7.3%	2.2%
Global Large-cap Pharma (mkt-cap wt avg)														
										12.9	8.8	4.0%	9.0%	2.7%

Source: Citi Research. Factset data for AbbVie

Appendix A-1

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