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Lilly avoids head-to-head collision with Novo's market leader

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No doubt the sighs of relief were palpable at Eli Lilly when results from the Award 6 trial came in. The high-risk, head-to-head study pitted the company's new GLP-1 agonist dulaglutide against Novo Nordisk's Victoza, and found that it performed just as well at reducing blood sugar in type II diabetics.

Although the study did not find any evidence of superiority, this is the first time another GLP-1 has measured up to the Danish company's market leader; a similar trial run by Bydureon's original owner Amylin had backfired spectacularly (*Amylin scores own goal in Bydureon vs Victoza head-to-head study, March 3, 2011*). As such, Lilly will be happy enough with the result, which should confirm analysts' forecasts that show dulaglutide becoming the second-biggest selling drug in this class by 2018 (see table).

Lilly shares were little changed on the news this morning – a non-inferiority reading was widely anticipated and a superiority finding was always considered a long shot. In the press release the company did not talk about the superiority data, but various analysts commented that it had confirmed that this was not hit.

Full data are due to be released at a medical meeting later this year and will be needed to measure the full impact of this trial. Blood sugar is of course important, but the drugs' effects on weight loss, heart rate and nausea – gastrointestinal tolerability is a big issue for this class – will also be closely scrutinised. Victoza is known to perform strongly on these measures, so dulaglutide will have to measure up here as well for this trial to have the sort of impact that Lilly hopes.

Meeting in the market

Approval is now the big event on the horizon for dulaglutide – decisions in the US and Europe are expected in late summer – and as is standard with diabetes drugs these days the regulators will no doubt be scrutinising the data package closely, particularly in terms of side effects. The phase III programme did not throw up anything particularly worrying, although blood pressure changes have been a concern.

But dulaglutide's efficacy data have been overwhelming positive. So far, Lilly's Award clinical programme has shown that dulaglutide, either alone or in various combinations, is superior or non-inferior to diabetes treatments ranging from Byetta to the long-acting insulin Lantus when it comes to controlling blood sugar.

The Award 6 study was always going to be hugely important in establishing the drug's place in a class that is getting increasingly crowded, and in which Victoza's domination is set to continue.

Lilly is no doubt hoping to build the drugs' dosing differences into an important differentiator; the Novo product is once daily. Consensus for dulaglutide sales sits at $850m in 2018, although *EvaluatePharma* data reveal that the more bullish analysts are expecting revenues of $1.3bn by that year.

The product has already been fingered as Lilly's most important growth driver. And while this head-to-head trial was run more for the marketing teams than the regulators, the company needed this result.

GLP-1 agonist market								
			Global sales ($m)					
Rank	**Product**	**Company**	**2014**	**2015**	**2016**	**2017**	**2018**	**Status**
1	Victoza	Novo Nordisk	2,630	3,033	3,416	3,717	4,021	Marketed
2	Dulaglutide	Eli Lilly	36	224	470	668	850	Filed
3	Bydureon	AstraZeneca	416	558	659	744	816	Marketed
4	Eperzan	GlaxoSmithKline	88	180	265	348	423	Filed
5	Lyxumia	Sanofi	93	151	222	289	342	Marketed
6	Byetta	AstraZeneca	322	289	227	192	171	Marketed
	Total		**3,674**	**4,436**	**5,259**	**5,957**	**6,624**	

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