Closer Look

MEMORANDUM

Novo Nordisk launches Tresiba (insulin degludec) in the US - January 26, 2016

Executive Highlights

- Novo Nordisk announced the launch of Tresiba (insulin degludec) in the US this morning.
- Tresiba has already secured Lowest Brand Co-pay status on the CVS national formulary and other payer negotiations are progressing.
- Per-unit cost for Tresiba is comparable to Levemir (insulin detemir), but is higher than Toujeo (U300 insulin glargine).

Novo Nordisk announced the US launch of next-generation basal insulin Tresiba (insulin degludec) this morning. The list price at our local CVS is $525.99 for a box of five FlexTouch pens containing the U100 formulation of Tresiba and $629.99 for a box of three pens of the U200 formulation (or $0.35 per unit for both formulations). The per-unit cost is comparable to Novo Nordisk's older basal insulin Levemir (insulin detemir), which is priced at $0.34 per unit. This is a bit surprising as Novo Nordisk previously indicated that it intended to price Tresiba at a 10% premium over Levemir; presumably, the comparable pricing is a reflection of the increasingly challenging payer environment in the US though Levemir prices continue to increase so it also may be a reflection of that. Indeed, the list price for a three-pen box of Sanofi's Toujeo (U300 insulin glargine) - Tresiba's most direct competitor - is $397.99 ($0.29 per unit of insulin, 20% lower than Tresiba's per-unit cost). That said, Tresiba's higher per-unit cost for many will be offset by the dose reduction observed vs. Sanofi's Lantus (insulin glargine) in phase 3 trials, in contrast to the dose increase seen with Toujeo. In other words, patients may require fewer units of Tresiba than Toujeo to achieve the same glycemic control. Tresiba's flexible dosing claim and longer duration of action will offer additional competitive advantages for some from a clinical standpoint. In terms of access, this morning's announcement noted that Novo Nordisk is moving quickly in payer negotiations for Tresiba and that the product has already secured Lowest Brand Co-pay status on CVS Health's national formulary. The company is also offering a Tresiba Instant Savings Card for commercially insured patients that would reduce co-pays to as low as $15/month for "up to" 24 months (Toujeo's Savings Card currently offers $15/month co-pays for 12 months).

The US arrival of Tresiba has been eagerly awaited - and long delayed. Novo Nordisk received a Complete Response Letter (CRL) from the FDA in February 2013 with a request for a pre-approval cardiovascular outcomes trial. The product was resubmitted in March 2015 and approved in September 2015. Tresiba has been available in the EU since early 2013 and has received favorable reviews from patients and providers, though penetration has been limited in countries where reimbursement is poor. After a long, arduous road, we're glad to finally see this product available in the US!

- **Reimbursement and access for Tresiba is a big question mark.** Novo Nordisk management has previously stated that the company does not intend to sacrifice price in exchange for broad access in the US and even suggested that price increases may be possible in the future. (In contrast, Sanofi was able to secure early, broad access for Toujeo in exchange for fairly high rebates.) When Tresiba launched in the UK in 2013, Novo Nordisk chose to price the product at a ~60%-70% premium over Levemir and Lantus, ostensibly to correct for the relative underpricing of insulin analogs in the region. This stance has presented challenges for Novo Nordisk in the past - the company announced in July that it would withdraw Tresiba from the German market following an IQWiG/G-BA decision that Tresiba offers no added benefit over existing options. In the company's

November Capital Markets Day, management shared that the withdrawal has been postponed for now, pending ongoing negotiations with the German government on the product. Nonetheless, it's clear that not all payers may feel that the value proposition of Tresiba is worth a price premium. Based on the local list price noted above, it appears that Novo Nordisk may have indeed compromised on price to some degree in order to gain access in the US.

- **Tresiba faces a crowded basal insulin landscape in an increasingly price-conscious payer environment.** Tresiba is arriving on the US market about a year behind Toujeo and it will presumably take some time for it to achieve comparable formulary access. In addition, while Lantus' sales have sharply declined in recent quarters, the product still accounted for 68% of basal insulin sales as of 3Q15. Adding to the uncertainty, Lilly/BI's biosimilar insulin glargine Basaglar will launch in the US in December 2016. In the markets where it has already launched, the biosimilar has been priced at a 15%-20% discount relative to Lantus, which may offer a welcome reprieve for patients and providers increasingly frustrated with rising insulin costs. Indeed, at IDF 2015, Dr. Matthew Riddle (Oregon Health and Science University, Portland, OR) estimated that 50% of patients with type 2 diabetes on insulin therapy could benefit from lower-cost biosimilar insulin, compared to a mere 25% for "next-generation" basal insulins such as Tresiba and Toujeo. Novo Nordisk will likely have to convince patients and providers of a substantial clinical advantage with Tresiba to justify a higher cost relative to competitors.
- **Novo Nordisk management has expressed great enthusiasm over Tresiba's US prospects in the past.** At the November Capital Markets Day, US EVP Mr. Jesper Høiland boasted that Tresiba's profile exactly matches that of the ideal next-generation insulin described at a meeting a decade ago in which management asked what insulin the company would need to compete in the coming years.
- **Novo Nordisk's GLP-1 agonist/basal insulin combination Xultophy (insulin degludec/liraglutide) is under FDA review, with a decision expected in 3Q16.** Xultophy was submitted to the FDA at the time of Tresiba's approval. Like Tresiba, Xultophy was approved and launched in the EU much earlier than in the US and has been available in those markets since late 2014.

Close Concerns Questions

Q: How will patients and providers view Tresiba?

Q: How are formulary negotiations with Express Scripts and UnitedHealthcare progressing?

Q: Will Novo Nordisk be able to "stick to its guns" and avoid high rebates for Tresiba?

Q: What sort of outreach to patients and/or providers does Novo Nordisk have planned for Tresiba?

Q: Is a direct-to-consumer campaign in the works?

Q: How might Tresiba's performance affect or foreshadow Xultophy sales?

-- by Helen Gao, Emily Regier, and Kelly Close