Closer Look

MEMORANDUM

Xultophy (IDegLira; insulin degludec/liraglutide) approved in Europe - September 18, 2014

Novo Nordisk announced today that the EMA has approved Xultophy (IDegLira; insulin degludec/liraglutide fixed-ratio combination), making it the first GLP-1 agonist/basal insulin combination product to reach the market. The company anticipates a launch beginning in 1H15 - discussions with the fragmented European government/payer environment can be time-consuming. Xultophy is indicated for the treatment of adults with type 2 diabetes mellitus to improve glycemic control in combination with oral glucose-lowering medicinal products when these alone or combined with basal insulin do not provide adequate glycemic control - this is a fairly broad indication, although it currently excludes patients currently on oral agents and a GLP-1 agonist, though we suspect there is potential for an expanded indication based on results from the DUAL III trial, which examines the added benefit of switching to Xultophy in patients on a GLP-1 agonist. We are incredibly excited to see this product finally so close to reaching patients, as the phase 3 data package for Xultophy is one of the strongest we have seen in the recent past for a diabetes therapy in terms of both efficacy (1.8% A1c reduction from baseline at one year in DUAL I) and safety. Based on comments from this year's ADA Analyst Call, it appears that Novo Nordisk is looking to price Xultophy based on a sum-of-its-parts model; it remains to be seen how this will be received in the challenging European reimbursement environment that has not proved wholly receptive to the pricing premium for Tresiba. Nonetheless, it is hard to ignore the strong efficacy and safety profile that Xultophy brings to the table, and we would hazard a guess that it will be a hit with patients due to the convenience of fewer injections along will less nausea than Victoza and less hypoglycemia than Tresiba and with physicians because of the ease of use. A US filing for Xultophy is dependent on the re-submission of Tresiba, which is currently expected in mid-2015 after the completion of the DEVOTE cardiovascular outcomes trial - we do not know how long after Tresiba is resubmitted that the company plans to file Xultophy. Sanofi's LixiLan (insulin glargine/lixisenatide) is on track for a US filing by the end of 2015 (we have not received specific guidance on a European submission). For even more details on Xultophy's progress until now, read our report on the positive CHMP opinion the candidate received in July.