Novo Nordisk submits DEVOTE data to FDA for inclusion on Tresiba label - May 30, 2017

Over the weekend, Novo Nordisk announced the submission of a Supplemental New Drug Application (sNDA) to the FDA for the inclusion of DEVOTE trial data on the Tresiba label. Topline data from the DEVOTE cardiovascular outcomes trial (CVOT), released in November 2016, showed that Tresiba (insulin degludec) was non-inferior to Sanofi's Lantus (insulin glargine) in terms of CV impact, as measured by three-point MACE (non-fatal MI, non-fatal stroke, and CV death). The hazard ratio was 0.91 in favor of Tresiba, meeting the trial's primary endpoint, though this did not reach statistical significance for superiority (nor was it expected to). In addition to CV effects, the announcement of topline data included details on hypoglycemia results: Tresiba was associated with a 40% reduced risk for severe hypoglycemia, and with a 54% reduced risk for severe nocturnal hypoglycemia vs. Lantus. If this label update is approved - and assuming a standard FDA review process, that decision should come in late 1Q18 or early 2Q18 - patients/providers will have more reassurance on the CV safety of Tresiba and on its distinct hypoglycemia benefit. This latter point could be particularly valuable in the real world. Novo Nordisk has also submitted an sNDA to include SWITCH data on the Tresiba label, which demonstrates significant reductions in symptomatic hypoglycemia vs. Lantus in type 1 as well as type 2 diabetes. The EMA has already approved a SWITCH label update, and an FDA decision is expected by September 2017. We imagine that a combination of DEVOTE and SWITCH data on this product label would definitively establish Tresiba's hypoglycemia benefit within the diabetes community, making it the basal insulin treatment of choice for many patients who are prone to hypoglycemia, who have impaired awareness of hypoglycemia, or who exhibit fear of hypoglycemia. That said, we expect the DEVOTE results, if accepted, will be included in the data section of the label rather than as a more prominent indication. It remains to be seen how the SWITCH data might be positioned on the US label. Full DEVOTE results will be presented at ADA 2017 in less than two weeks (see our full conference preview and our category document on insulin therapy).

-- by Payal Marathe, Helen Gao, and Kelly Close