European CHMP endorses inclusion of LEADER data on label for Novo Nordisk's Saxenda (liraglutide 3.0 mg for obesity) - June 22, 2017

In a surprise move today, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) endorsed the inclusion of LEADER trial data on the label for Novo Nordisk's obesity medication Saxenda (liraglutide 3.0 mg). This news is certainly welcome, but is somewhat unexpected considering that the LEADER cardiovascular outcomes trial (CVOT) evaluated the long-term impact of lower doses of liraglutide (1.2 mg and 1.8 mg, branded as Victoza for type 2 diabetes). Further, the LEADER trial specifically enrolled only patients with type 2 diabetes at relatively high cardiovascular risk - while we expect the results apply to patients with obesity and high CV risk as well (who may not necessarily have type 2 diabetes), this has not been explicitly assessed in a randomized, controlled trial. That said, the CHMP previously concluded that the results of LEADER would be sufficient to support the CV safety of Saxenda and Saxenda would not be required to undergo a separate CVOT. It's unclear how the LEADER results - which demonstrated the superiority, not just non-inferiority - of Victoza for CV risk - will be incorporated into the label - we assume it will be included in the "clinical efficacy and safety" section of the label, rather than as an updated indication. Novo Nordisk has also submitted the LEADER data to the FDA and EMA in hopes of an updated indication of CV risk reduction on the Victoza label - the announcement today noted that Novo Nordisk expects to receive a response from the EMA on the proposed Victoza indication "shortly." Earlier this week, the FDA convened an Advisory Committee meeting to discuss the proposed indication for Victoza - while the discussion was fairly contentious (focusing in on some heterogeneity in subgroup analyses of the CV results), the panel ultimately voted 17-2 in favor of an updated indication.

-- by Helen Gao and Kelly Close