Teva files abbreviated NDA for a generic version of Victoza (liraglutide) - February 9, 2017

Teva Pharmaceutical Industries announced that it has filed an abbreviated new drug application (ANDA) with the FDA recently seeking approval to market a generic version of Novo Nordisk's Victoza (liraglutide). To our knowledge, Teva is the first to file such an ANDA, and in doing so, Teva is challenging Novo Nordisk's patents for Victoza (the first of which is set to expire in August 2017). If the company's filing is approved, Teva will be entitled to 180 days of generic market exclusivity. In addition to boasting a cardioprotective benefit, as demonstrated in the recent LEADER CVOT, Victoza is a blockbuster drug, posting sales of nearly $3 billion in 2016 according to Novo Nordisk's most 4Q16 and full year earnings update. High-growth Victoza currently dominates the US GLP-1 agonist arena with 50% market share by volume in terms of total prescriptions (TRx). The underlying growth of the overall GLP-1 agonist market is an advantage for Teva in its attempt to break into GLP-1 generics; the GLP-1 agonist market has increased to nearly 10% of the value share of the total diabetes care market (from 8% at the end of 2015) and even higher, close to 12% in the US; overall volume growth for GLP-1 agonists in the US market continues to hover around 30%. Victoza's clinical profile is extremely impressive, particularly in terms of cardiovascular protection, weight loss, and hypoglycemia, but pricing and access has been an ongoing concern. We will be interested to see what happens next with a generic version; safety and quality assurance for biosimilars remain an ongoing question and discounts for biologic biosimilars in diabetes have so far been far smaller than those of small molecule generics.

-- by Abigail Dove, Helen Gao, and Kelly Close