Victoza® (liraglutide) – New indication, new warning

- On August 25, 2017, Novo Nordisk announced the FDA approval of Victoza (liraglutide), to reduce the risk of major adverse cardiovascular (CV) events [CV death, non-fatal myocardial infarction (MI), or non-fatal stroke] in adults with type 2 diabetes mellitus (T2DM) and established CV disease.
  - Previously, Victoza was only indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.
  - Victoza is not a substitute for insulin. Victoza should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
  - The concurrent use of Victoza and prandial insulin has not been studied.
- Approval for the new indication was based on the results from the LEADER study - a randomized, double-blind, placebo-controlled trial that enrolled 9,340 patients with T2DM at high risk of major adverse CV events. Patients received standard of care plus Victoza (up to 1.8 mg daily) or placebo and were followed for 3.5 – 5 years. The primary endpoint was the first occurrence of a composite CV outcome comprising of CV death, non-fatal MI or non-fatal stroke.
  - The primary outcome occurred in significantly fewer patients in the Victoza group (13.0%) vs. placebo group (14.9%) (HR = 0.87; 95% CI: 0.78, 0.97; p < 0.001 for noninferiority; p = 0.01 for superiority).
- The Warnings and Precautions section was also updated with information regarding acute gallbladder disease.
  - In the LEADER trial, 3.1% of Victoza-treated patients vs. 1.9% of placebo-treated patients reported an acute event of gallbladder disease, such as cholelithiasis or cholecystitis. The majority of events required hospitalization or cholecystectomy.
  - If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.
- Victoza carries a boxed warning for risk of thyroid C-cell tumors.