## Victoza® (liraglutide) – Expanded indication

- On June 17, 2019, the FDA announced the approval of Novo Nordisk's Victoza (liraglutide), as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus (T2DM).
    - Previously, Victoza was approved for the same indication in adults only.
    - 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.
- Victoza is also approved to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with T2DM and established cardiovascular disease.
- The approval of Victoza for the expanded indication was based on a 26-week, double-blind study of 134 pediatric patients with T2DM aged 10 years and older. Patients were randomized to Victoza or placebo once-daily in combination with metformin with or without basal insulin treatment.
    - At week 26, treatment with Victoza reduced HbA1c by 0.64% vs. an increase of 0.42% for placebo (Treatment difference = -1.06; 95% CI: -1.65; -0.46; $p < 0.001$).
- Victoza carries a boxed warning for the risk of thyroid C-cell tumors.
- The recommended initial dose for Victoza in pediatric patients with T2DM is 0.6 mg daily. After at least one week at 0.6 mg daily, the dose may be increased to 1.2 mg daily if additional glycemic control is required. If additional glycemic control is required, the dose may be increased to 1.8 mg daily after at least one week of treatment with the 1.2 mg daily dose.
    - Refer to the Victoza drug label for adult dosing and additional administration recommendations.