Invokana® (canagliflozin), Invokamet/Invokamet® XR (canagliflozin/metformin) – Expanded indication

- On December 18, 2024, the FDA approved Janssen's Invokana (canagliflozin) and Invokamet/Invokamet XR (canagliflozin/metformin), as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with **type 2 diabetes mellitus**.
    - Invokana and Invokamet/Invokamet XR were previously approved for this indication in adults only. **This update expands the approval to include pediatric patients aged 10 years and older**.
- Canagliflozin is also approved:
    - To reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease
    - To reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day.
- The approval of these products for the expanded indication was based on a double-blind, placebo-controlled study in 171 pediatric patients aged 10 to 17 years with inadequately controlled type 2 diabetes mellitus. Patients were randomized to Invokana or placebo. The primary endpoint was the change in HbA_{1c} at week 26.
    - At week 26, the change from baseline in HbA_{1c} was -0.38 with Invokana vs. +0.34 with placebo (difference -0.73, 95% CI: -1.26, -0.19; p = 0.008).
- Invokamet/Invokamet XR carry a boxed warning for lactic acidosis.
- The recommended **starting dosage of Invokana for glycemic control is 100 mg orally once daily**, taken before the first meal of the day. For additional glycemic control, the dose may be increased to the **maximum recommended dosage of 300 mg once daily**.
    - Refer to the Invokamet/Invokamet XR drug label for its dosing and to the Invokana drug label for its other indications.