Invokana® (canagliflozin), Invokamet® (canagliflozin/metformin) and Invokamet XR (canagliflozin/metformin extended-release) – Label updates

- On August 18, 2020, the FDA approved updates to the drug labels for Invokana (canagliflozin), Invokamet (canagliflozin/metformin) and Invokamet XR (canagliflozin/metformin extended-release) regarding the removal of the boxed warning for lower limb amputation and the removal of the albuminuria condition for continued dosing of patients whose estimated glomerular filtration rate (eGFR) falls between 30 and less than 45 mL/min/1.73 m^2.

- Invokana, Invokamet (canagliflozin/metformin), and Invokamet XR (canagliflozin/metformin extended-release) are indicated for the following:

    — As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
    — 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

- Invokana, Invokamet and Invokamet XR are not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

- Invokana is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m^2. Invokana is likely to be ineffective in this setting based upon its mechanism of action.

- Invokamet and Invokamet XR carry a boxed warning for lactic acidosis.

- Refer to the drug labels for dosage recommendations based on eGFR.