## Synjardy®, Synjardy XR® (empagliflozin/metformin) – New Indication

- On December 23, 2016, the FDA approved Boehringer Ingelheim's Synjardy (empagliflozin/metformin) and Synjardy XR (empagliflozin/metformin extended-release) to reduce the risk of cardiovascular (CV) death in adults with type 2 diabetes mellitus (T2DM) and established CV disease.
    - Previously, Synjardy and Synjardy XR were only approved as an adjunct to diet and exercise to improve glycemic control in adults with T2DM when treatment with both Jardiance® (empagliflozin) and metformin is appropriate.
    - The effectiveness of Synjardy and Synjardy XR on reducing the risk of cardiovascular death in adults with T2DM and CV disease has not been established.
    - Synjardy and Synjardy XR are not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

- The newly approved indication for Synjardy and Synjardy XR was based on the EMPA-REG OUTCOME® postmarketing study required by the FDA. The study involved more than 7,000 patients with T2DM and CV disease. In the trial, Jardiance demonstrated significant reductions in CV risk and CV death.
    - When added to standard of care, Jardiance significantly reduced the risk of the combined endpoint (CV death, non-fatal myocardial infarction [MI], or non-fatal stroke) by 14% vs. placebo.
    - In addition, there was a 38% risk reduction in CV death and a 32% risk reduction in all-cause mortality vs. placebo.

- Like other metformin-containing products, Synjardy and Synjardy XR carry a boxed warning for lactic acidosis.