



### Jardiance® (empagliflozin) – New Indication

- On December 2, 2016, the [FDA announced](#) the approval of Eli Lilly and Boehringer Ingelheim's [Jardiance \(empagliflozin\)](#) tablets, to reduce the risk of cardiovascular (CV) death in adult patients with type 2 diabetes mellitus (T2DM) and CV disease.
  - Previously, Jardiance was only approved as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.
- According to the [Centers for Disease Control and Prevention](#), there are 29.1 million Americans who have diabetes.
  - Death from CV disease is 70% higher in adults with diabetes vs. those without diabetes. Patients with diabetes have a decreased life expectancy driven in large part by premature CV death.
- The newly approved indication for Jardiance 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 compared to placebo.



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