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KIDNEY WEEK 2022

# EMPEROR CLINICAL TRIAL DATA SUBGROUP ANALYSES AND DOSING RECOMMENDATIONS FOR ADULTS WITH HF AND/OR T2DM

Background and clinical trial data on JARDIANCE focusing on subgroup analyses, such as T2DM status and by baseline eGFR, as well as a focus on initiation, dosing and guidance for monitoring patients on JARDIANCE.

Attendees will have the opportunity to ask the faculty questions about the data presented.

**THURSDAY, NOVEMBER 3, 2022**

10:00 AM - 10:45 AM

## Exhibitor Spotlight Theater #1

Exhibit Hall, West Building, Level 2  
Orange County Convention Center  
Orlando, FL

### LEARN MORE ABOUT JARDIANCE AT [JARDIANCEhcp.com](http://JARDIANCEhcp.com)

This presentation is supported by and made on behalf of Boehringer Ingelheim Pharmaceuticals, Inc. and Lilly USA, LLC. Presentation content has been reviewed for consistency with FDA guidelines and is not approved for continuing medical education credit. Speakers receive fair market value compensation for this presentation.

Pursuant to the PhRMA (Pharmaceutical Research and Manufacturers of America) Code on Interactions with Healthcare Professionals, attendance by healthcare professionals' spouses or guests is not permitted.

**The Exhibitor Spotlight is not a Continuing Education (CE) activity.**

#### INDICATIONS AND LIMITATIONS OF USE

JARDIANCE is indicated:

- to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
- to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.
- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

JARDIANCE is not recommended in patients with type 1 diabetes mellitus. It may increase their risk of diabetic ketoacidosis.

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

#### IMPORTANT SAFETY INFORMATION

**CONTRAINDICATIONS:** Hypersensitivity to empagliflozin or any of the excipients in JARDIANCE, reactions such as angioedema have occurred; patients on dialysis.

Please see additional Important Safety Information on reverse. Please see accompanying [Prescribing Information](#), including [Medication Guide](#) for JARDIANCE.

eGFR, estimated glomerular filtration rate; HF, heart failure; T2DM, type 2 diabetes mellitus.

**Jardiance**<sup>®</sup>  
(empagliflozin) tablets  
10 mg/25 mg



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## WARNINGS AND PRECAUTIONS

**Ketoacidosis:** Ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, has been identified in patients with type 1 and type 2 diabetes mellitus receiving SGLT2 inhibitors, including empagliflozin. Fatal cases of ketoacidosis have been reported in patients taking empagliflozin. Patients who present with signs and symptoms of metabolic acidosis should be assessed for ketoacidosis, even if blood glucose levels are less than 250 mg/dL. If suspected, discontinue JARDIANCE, evaluate, and treat promptly. Before initiating JARDIANCE, consider risk factors for ketoacidosis. Patients may require monitoring and temporary discontinuation in situations known to predispose to ketoacidosis. For patients who undergo scheduled surgery, consider temporarily discontinuing JARDIANCE for at least 3 days prior to surgery.

**Volume Depletion:** Empagliflozin can cause intravascular volume depletion which may manifest as symptomatic hypotension or acute transient changes in creatinine. Acute kidney injury requiring hospitalization and dialysis has been reported in patients with type 2 diabetes receiving SGLT2 inhibitors, including empagliflozin. Before initiating, assess volume status and renal function in patients with impaired renal function (eGFR <60 mL/min/1.73 m<sup>2</sup>), elderly patients or patients on loop diuretics. In patients with volume depletion, correct this condition. After initiating, monitor for signs and symptoms of volume depletion and renal function.

**Urosepsis and Pyelonephritis:** Serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization have been identified in patients receiving SGLT2 inhibitors, including empagliflozin. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate for signs and symptoms of urinary tract infections and treat promptly.

**Hypoglycemia: The use of JARDIANCE in combination with insulin or insulin secretagogues** can increase the risk of hypoglycemia. A lower dose of insulin or the insulin secretagogue may be required.

### **Necrotizing Fasciitis of the Perineum (Fournier's Gangrene):**

Serious, life-threatening cases requiring urgent surgical intervention have occurred in both females and males. Serious outcomes have included hospitalization, multiple surgeries, and death. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, institute prompt treatment and discontinue JARDIANCE.

**Genital Mycotic Infections:** Empagliflozin increases the risk for genital mycotic infections, especially in patients with prior infections. Monitor and treat as appropriate.

**Hypersensitivity Reactions:** Serious hypersensitivity reactions have occurred with JARDIANCE (angioedema). If hypersensitivity reactions occur, discontinue JARDIANCE, treat promptly, and monitor until signs and symptoms resolve.

**MOST COMMON ADVERSE REACTIONS (≥5%):** Urinary tract infections and female genital mycotic infections.

**DRUG INTERACTIONS:** Coadministration with diuretics may enhance the potential for volume depletion. Monitor for signs and symptoms.

### **USE IN SPECIAL POPULATIONS**

**Pregnancy:** JARDIANCE is not recommended during the second and third trimesters.

**Lactation:** JARDIANCE is not recommended while breastfeeding.

**Geriatric Use:** JARDIANCE is expected to have diminished glycemic efficacy in elderly patients with renal impairment. Renal function should be assessed more frequently in elderly patients. The incidence of volume depletion-related adverse reactions and urinary tract infections increased in T2D patients ≥75 years treated with empagliflozin.

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Please see additional Important Safety Information on reverse. Please see accompanying [Prescribing Information](#), including [Medication Guide](#) for JARDIANCE.

