

EMPA-KIDNEY

the study of heart and kidney protection with empagliflozin

Empagliflozin is not indicated for heart and kidney protection.

STUDY OBJECTIVE¹

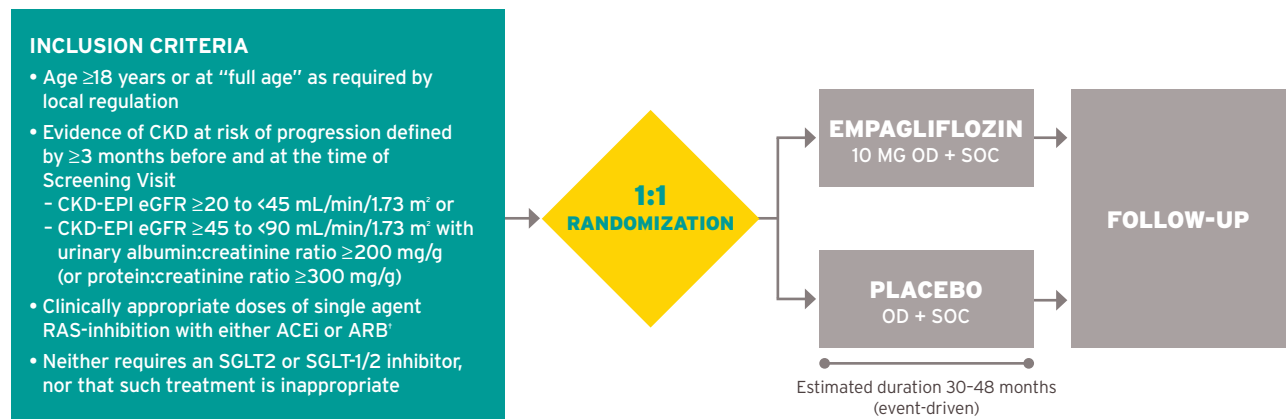
To investigate the effect of empagliflozin on kidney disease progression or cardiovascular death vs. placebo on top of standard of care (SOC) in patients with pre-existing chronic kidney disease.

PRIMARY ENDPOINT¹

Composite primary outcome: Time to first occurrence of (i) Kidney disease progression (defined as ESKD*, a sustained decline in eGFR to <10 mL/min/1.73 m², renal death, or a sustained decline of $\geq 40\%$ in eGFR from randomization) or (ii) Cardiovascular death.

STUDY DESIGN^{1,2}

Phase III, randomized, double-blind, placebo-controlled trial



JARDIANCE® is indicated as an adjunct to diet, exercise and standard care therapy to reduce the incidence of cardiovascular death in patients with type 2 diabetes mellitus and established cardiovascular disease.³

eGFR=estimated glomerular filtration rate; CKD=chronic kidney disease; CKD-EPI=chronic kidney disease epidemiology collaboration; RAS=renin-angiotensin system; ACEi=angiotensin-converting enzyme inhibitor; ARB=angiotensin-receptor blocker; SGLT2=sodium-glucose co-transporter 2; SGLT-1/2=sodium-glucose co-transporter 1/2; OD=once daily. * End Stage Kidney Disease (ESKD) is defined as the initiation of maintenance dialysis or receipt of a kidney transplant.

† Unless such treatment is either not tolerated or not indicated.

Monotherapy: JARDIANCE® (empagliflozin) is indicated for use as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus for whom metformin is inappropriate due to contraindications or intolerance.³

Add-on combination: JARDIANCE® is indicated in adult patients with type 2 diabetes mellitus to improve glycemic control, when metformin used alone does not provide adequate glycemic control, in combination with: metformin, metformin and a sulfonylurea, pioglitazone (alone or with metformin), linagliptin and metformin, basal or prandial insulin (alone or with metformin), when the existing therapy, along with diet and exercise, does not provide adequate glycemic control.³

Consult the Product Monograph at www.JardiancePM.ca for important information about:³

- Contraindications in patients with severe renal impairment (eGFR <30 mL/min/1.73 m²), end-stage renal disease, and patients on dialysis
- Most serious warnings and precautions regarding diabetic ketoacidosis (DKA), a serious, life-threatening condition requiring urgent hospitalization. Fatal cases of DKA have been reported in patients taking JARDIANCE®.

- Other relevant warnings and precautions regarding patients with type 1 diabetes; patients at risk for volume depletion; patients at high risk for cerebrovascular accidents; use in situations predisposing to ketoacidosis; when reducing concomitant insulin dose; use in combination with insulin secretagogues or insulin; increases in LDL-C; genital mycotic infections; urinary tract infections; necrotizing fasciitis of the perineum (Fournier's gangrene); patients with elevated hematocrit; patients with severe hepatic impairment; serious hypersensitivity reactions; renal function abnormalities; acute kidney injury; use in settings of reduced oral intake or fluid loss; use in pregnant or nursing women, pediatrics, and geriatrics; and glucose in urine
- Conditions of clinical use, adverse reactions, drug interactions and dosing instructions

The Product Monograph is also available by calling 1-800-263-5103 ext. 84633.

LDL-C=low-density lipoprotein cholesterol.

References: 1. U.S. National Library of Medicine - ClinicalTrials.gov. A study to test the effect of empagliflozin in patients who are in hospital for acute heart failure. Available at: <https://clinicaltrials.gov/ct2/show/NCT04157751?term=EMPULSE&draw=1&rank=1>. 2. Data on file, Boehringer Ingelheim (Canada) Ltd. 3. JARDIANCE® Product Monograph, Boehringer Ingelheim (Canada) Ltd., April 15, 2020.

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Jardiance®
(empagliflozin)