ONGOING STUDY

Jardiance® (empagliflozin)

EMPULSE

the study evaluating the effect of empagliflozin in patients hospitalized for acute HF

Empagliflozin is not indicated in HF or in patients hospitalized for acute HF.*

STUDY OBJECTIVE[1]

To evaluate the effect of empagliflozin vs. placebo on HF-related clinical events and patient-reported outcomes (death, HFE and KCCQ-TSS) as a measure of health status (symptoms) in patients hospitalized for acute HF (de novo or decompensated chronic HF) who have been stabilized.

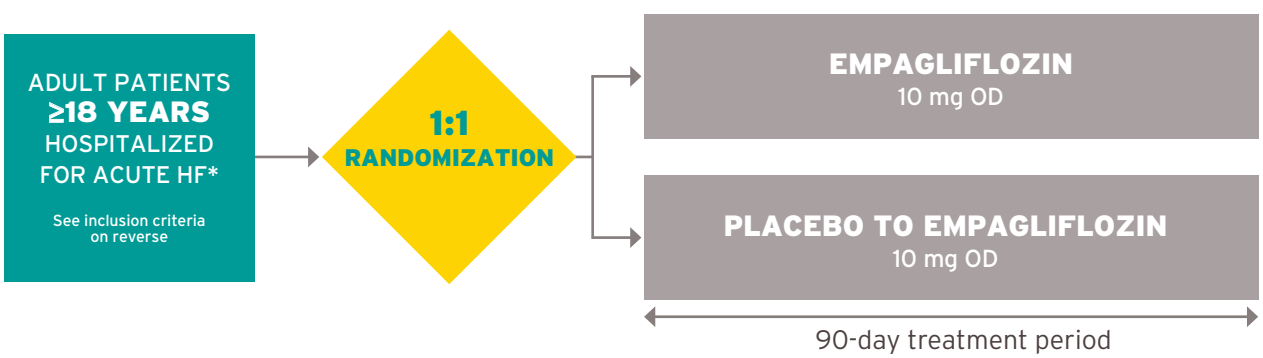
PRIMARY ENDPOINT[1]

Composite endpoint composed of:

- Death
- Number of HFEs (including hospitalizations for HF, urgent HF visits and unplanned outpatient visits)
- Time to first HFE
- Change from baseline in KCCQ-TSS after 90 days of treatment

STUDY DESIGN[1]

Phase III, multicentre, randomized, double-blind, 90-day superiority 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.[2]

HF=heart failure; HFE=heart failure event; KCCQ-TSS=Kansas City Cardiomyopathy Questionnaire – Total Summary Score; OD=once daily.
* De novo or decompensated chronic HF.

INCLUSION CRITERIA*

- Currently hospitalized for primary diagnosis of acute HF (de novo or decompensated chronic HF), regardless of EF†
- Evidence of LVEF (either reduced or preserved EF) as per local reading‡
- Must be randomized after ≥24 hours and no later than 5 days after admission, as early as possible after stabilization and while still in hospital
- Must fulfill stabilization criteria (while in the hospital)§
- Elevated NT-proBNP ≥1,600 pg/mL or BNP ≥400 pg/mL according to the local lab, for patients without AF; or elevated NT-proBNP ≥2,400 pg/mL or BNP ≥600 pg/mL for patients with AF, measured during the current hospitalization or in 72 hours prior to hospital admission¶
- HF episode leading to hospitalization must have been treated with ≥40 mg dose of I.V. furosemide (or equivalent I.V. loop diuretic||)
- Further inclusion criteria apply

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.[2]

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.[2]

Consult the Product Monograph at www.JardiancePM.ca for important information about:[2]

- Contraindications in patients with severe renal impairment (eGFR <30 mL/min/1.73 m^2), 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.

EF=ejection fraction; LVEF=left ventricular ejection fraction; NT-proBNP=N-terminal pro b-type natriuretic peptide; BNP=B-type natriuretic peptide; AF=atrial fibrillation; I.V.=intravenous; eGFR=estimated glomerular filtration rate; LDL-C=low-density lipoprotein cholesterol; SBP=systolic blood pressure.
* Further inclusion criteria apply.
† Patients with a diagnosis of hospitalized HF must have HF symptoms at time of hospital admission.
‡ Preferably measured during current hospitalization or in 12 months prior to randomization.
§ Stabilization criteria: SBP ≥100 mmHg and no symptoms of hypotension in preceding 6 hours; no increase in I.V. diuretic dose for 6 hours prior to randomization; no I.V. vasodilators including nitrates within last 6 hours prior to randomization; no I.V. inotropic drugs for 24 hours prior to randomization.
¶ For patients treated with an angiotensin receptor neprilysin inhibitor (ARNI) in the previous 4 weeks prior to randomization, only NT-proBNP values should be used.
|| Defined as 20 mg of torasemide or 1 mg of bumetanide.

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. JARDIANCE® Product Monograph, Boehringer Ingelheim (Canada) Ltd., April 15, 2020.

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Jardiance® (empagliflozin)

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