DELIVER: The largest and broadest HFpEF trial to date

in patients with LVEF >40%[1]

DELIVER

Study design[2,3]

Phase III, international, multicenter, randomized, double-blind, parallel-group study

- Age ≥40 with/without T2D
- LVEF >40%[a] and evidence of structural heart disease[b]
- Symptomatic HF NYHA class II–IV
- Ambulatory or hospitalized[c]
- Elevated NT-proBNP levels
- eGFR ≥25 mL/min/1.73 m²

Randomized 1:1

N=6263

DAPA 10 mg

Median follow-up: 2.3 years

Placebo

Baseline characteristics[1]

Reflective of patient populations seen in daily practice

1011 pg/mL
Median NT-proBNP

54%
Average LVEF

55%
Without T2D

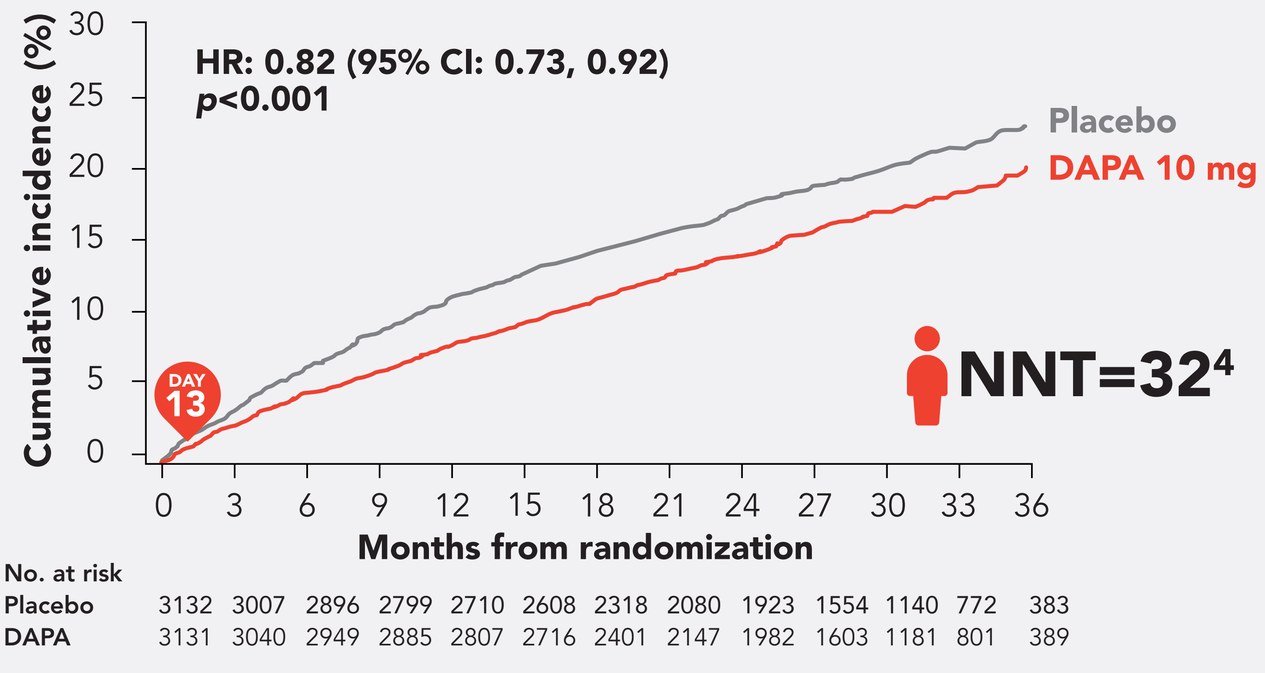
50%
eGFR <60 mL/min/1.73 m²

10%
Hospitalized or recently discharged

~18%
Improved ejection fraction[d]

Primary endpoint[3]

Significant reduction in composite of CV death or worsening HF[e]



NNT=32[4]

18% RRR

3.1% ARR
***p*=0.0008[4]**

- Findings were consistent across prespecified subgroups
- All individual components occurred less frequently in the DAPA group although CV death was not statistically significant
- Significant clinical benefit observed as early as Day 13[5,f]

Adapted from Solomon SD, et al. 2022.[3]

Secondary endpoints[3]

Significant reduction in total[g] worsening HF events[e] or CV deaths
RR: 0.77 (95% CI: 0.67, 0.89); *p*<0.001

Significant improvement in HF symptoms
Change in KCCQ-TSS at 8 months
Win ratio: 1.11 (95% CI: 1.03, 1.21); *p*=0.009

Mortality rates numerically lower
CV death
HR: 0.88 (95% CI: 0.74, 1.05)*
All-cause death
HR: 0.94 (95% CI: 0.83, 1.07)*

*Not statistically significant

Safety outcomes[3]

Safety was consistent with the well-established profile of DAPA

Event, n (%)	DAPA 10 mg n=3126[g]	Placebo n=3127[h]
SAE[i]	1361 (43.5)	1423 (45.5)
DAE	182 (5.8)	181 (5.8)
Amputation	19 (0.6)	25 (0.8)
Major hypoglycemic event	6 (0.2)	7 (0.2)
Diabetic ketoacidosis[j]	2 (0.1)	0 (0)
Volume depletion SAE or DAE	42 (1.3)	32 (1.0)
Renal SAE or DAE	73 (2.3)	79 (2.5)
Fournier's gangrene	0 (0)	0 (0)

[a]Prior LVEF ≤40% also included; [b]Left ventricular hypertrophy or left atrial enlargement; [c]Off IV HF therapy (including diuretics) for ≥24 hours; [d]Prior LVEF ≤40%; [e]hHF or urgent HF visit; [f]Time to first nominal statistical significance for primary endpoint. Benefit was sustained from day 15 onward; [g]First and recurrent; [h]Includes patients who underwent randomization and received at least 1 dose of study medication; [i]Including death; [j]All cases were adjudicated as definite or probable.

ARR, absolute risk reduction; CI, confidence interval; CV, cardiovascular; DAE, discontinuation due to adverse event; DAPA, dapagliflozin; eGFR, estimated glomerular filtration rate; HF, heart failure; hHF, hospitalization for heart failure; HR, hazard ratio; IV, intravenous; KCCQ-TSS, Kansas City Cardiomyopathy Questionnaire Total Symptom Score; LVEF, left ventricular ejection fraction; NNT, number needed to treat; NT-proBNP, N-terminal proB-type natriuretic peptide; NYHA, New York Heart Association; RR, rate ratio; RRR, relative risk reduction; SAE, serious adverse event; T2D, Type 2 diabetes.

References: 1. Solomon SD, et al. JACC Heart Fail 2022;10(3):184–197; **2.** Solomon SD, et al. Eur J Heart Fail 2021;23(7):1217–1225; **3.** Solomon SD, et al. N Engl J Med 2022;387:1089–1098; **4.** Solomon SD. Presented at ESC Congress, August 26-29, 2022; Barcelona, España; **5.** Vaduganathan M, et al. JAMA Cardiol 2022;1259–1263

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