

EQUINOX-HFpEF: A Phase 2 Study of EDG-15400, a Selective Cardiac Sarcomere Modulator, in Adults with Heart Failure with Preserved Ejection Fraction



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clinicaltrials.gov/study/NCT07795814
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Background

Heart failure with preserved ejection fraction (HFpEF) is a heterogeneous syndrome characterized by impaired ventricular relaxation and reduced compliance, leading to elevated left ventricular filling pressures, despite preserved ejection fraction. Limited diastolic reserve is most evident during physiologic stress and higher heart rates.

EDG-15400 is an investigational, novel, oral, selective cardiac sarcomere modulator specifically designed to accelerate ventricular relaxation and improve LV compliance without compromising overall systolic function.

Trial Summary

- Phase 2 randomized, double-blind, placebo-controlled trial of EDG-15400 (25 or 50 mg once daily) in ~90 adults with symptomatic HFpEF.
- Evaluates safety, tolerability, PK, and biomarkers (NT-proBNP, hs-cTnI), with echo and functional exploratory measures.
- Recruiting now; LPLV expected Q4 2027 (NCT07795814).
- Builds on nonclinical diastolic-function benefit without systolic liability and favorable Phase 1 healthy-adult data.

Phase 1 presentation Mon 10/12 12:15 PM:

- EDG-15400, A Cardiac Sarcomere Modulator, Demonstrated Favorable Pharmacokinetics, Pharmacodynamics, and Tolerability in Healthy Adult Participants (M. Mok)

Key Eligibility

Key Inclusion

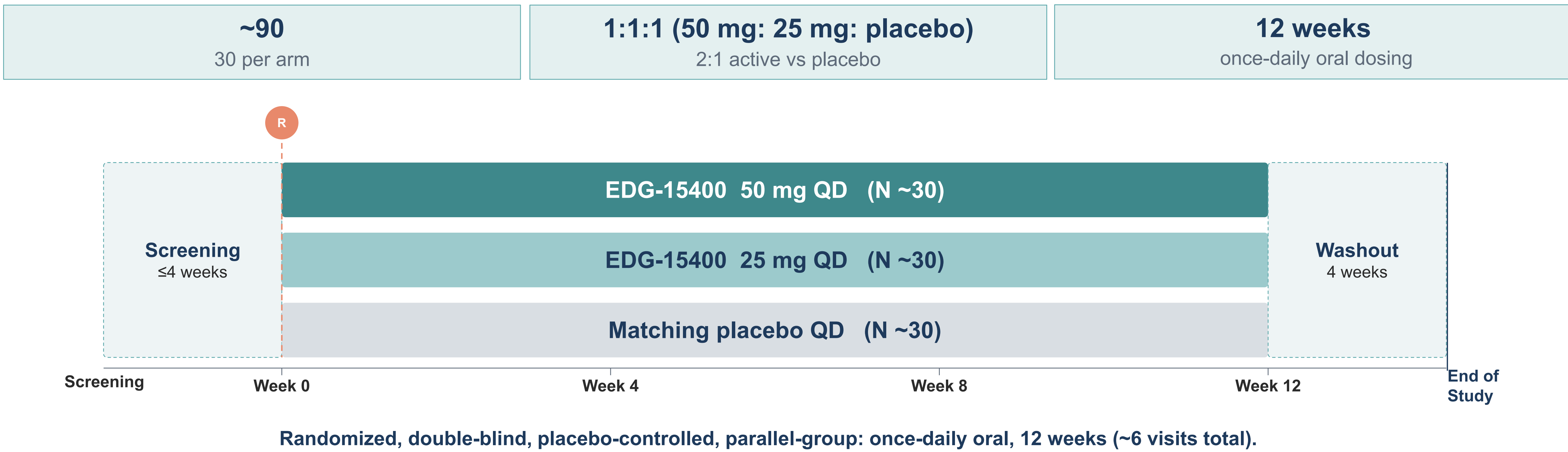
- Age ≥30 to <85 years
- Weight ≥45 kg; BMI <40
- LVEF ≥50% by core-lab echocardiography
- Diagnosed with HF per AHA/ACC/HFSA Guidelines
- NYHA class II–III

Key Exclusion

- Known HCM
- Known or suspected infiltrative/storage disorder
- Moderate/severe ILD or COPD requiring chronic supplemental O₂
- Hospitalization for any reason within 60 days prior to Screening

Study Design

- ▶ This first-in-patient Phase 2 study evaluates EDG-15400’s safety, tolerability, pharmacokinetics, and pharmacodynamics in adults with symptomatic HFpEF (NCT07795814)



Objectives & Endpoints

Primary:

- **Safety & tolerability:** incidence of TEAEs and SAEs, baseline through study completion

Secondary

- **Change in biomarkers:** change from baseline in NT-proBNP and hs-cTnI, baseline through study completion
- **EDG-15400 plasma concentrations:** Pre- and post-dose plasma concentrations measured throughout the study, from baseline through study completion

Assessments

- Visits: Screening → Wk 0 (R) → Wk 4 → Wk 8 → Wk 12 (EOT) → washout → EOS
- Echocardiography (Core Lab): Screening, Wk 4, Wk 12, EOS
- Biomarkers: NT-proBNP, hs-cTnI
- 6MWT; KCCQ-23; PGI-C/S; NYHA
- PK, local safety labs
- 12-lead ECG

Study Status

Status: Recruiting
Start: 25 Aug 2026
FPFV: 2H 2026 **LPLV:** Q4 2027
Primary completion expected: Dec 2027



Abbreviations

6MWT, 6-minute walk test; ACC, American College of Cardiology; AHA, American Heart Association; COPD, chronic obstructive pulmonary disease; EOS, end of study; EOT, end of treatment; FPFV, first patient first visit; hs-cTnI, high-sensitivity cardiac troponin I; ILD, interstitial lung disease; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVEF, left ventricular ejection fraction; LPLV, last patient last visit; NYHA, New York Heart Association; NT-proBNP, N-terminal pro-B-type natriuretic peptide; PD, pharmacodynamics; PGI-C/S, Patient Global Impression – Change and Severity; PK, pharmacokinetics; SAE, serious adverse event; TEAE, treatment-emergent adverse event; QD, once daily; Wk, week.

Disclosures

EDG-15400 is an investigational agent that is not approved for use by any regulatory authority in any territory. This study is funded by Edgewise Therapeutics. MG, KD, MA, AT, BC are employees of Edgewise Therapeutics.

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