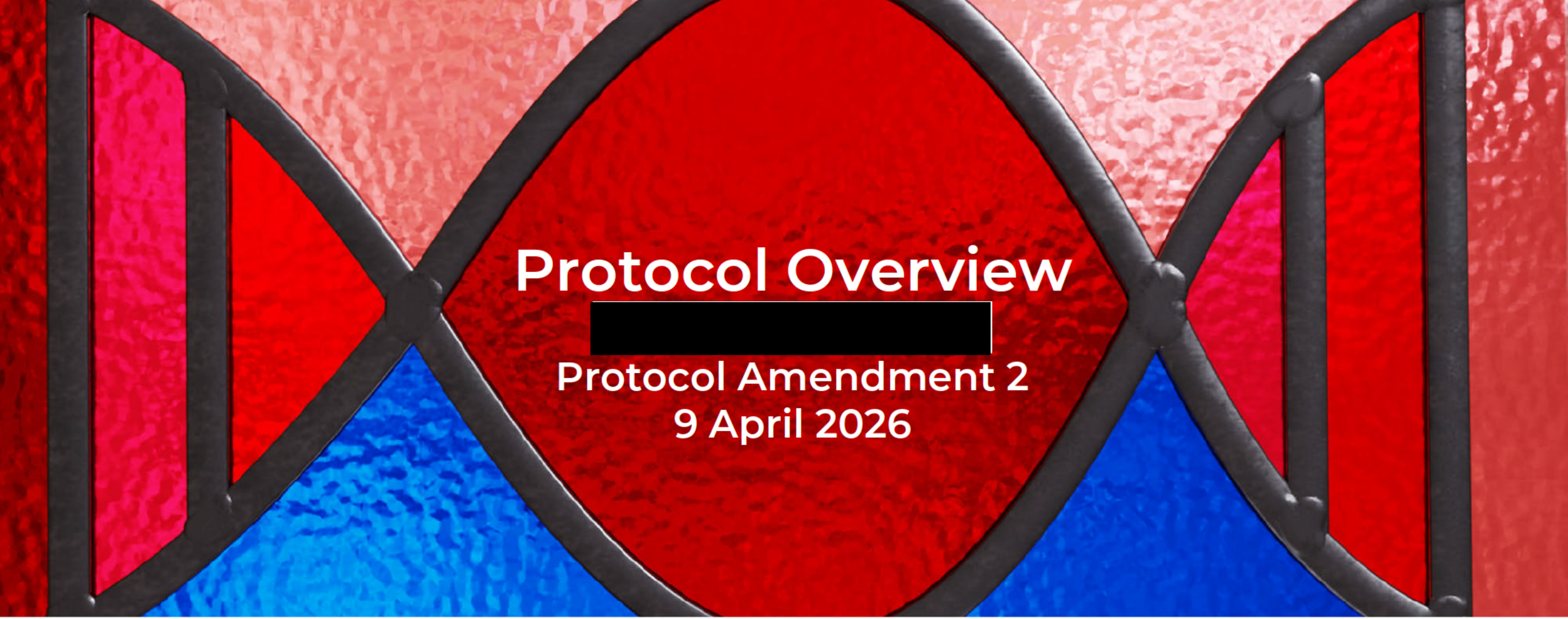

Protocol Overview

[redacted]

Protocol Amendment 2
9 April 2026

A [redacted] Study to Investigate [redacted] in Adult Participants with *BAG3* Mutation-Associated Dilated Cardiomyopathy (DCM).

[redacted]

[redacted]

Study Objective

The primary objectives of this study will be:

- **For Part A:** To determine safety and tolerability after a single IV infusion of [redacted] in participants with *BAG3*-associated DCM
- **For Part B:** To evaluate clinical impact (efficacy) after a single IV infusion of [redacted] vs. external control in participants with *BAG3*-associated DCM

[redacted]

Mechanism of Action for [redacted]

- The investigational medication, [redacted], is an Adeno-associated virus serotype 9 (AAV9) gene therapy intended for the treatment of DCM caused by mutations in *BAG3*
- [redacted] uses a cardiac Troponin T (cTnT) promoter to drive *BAG3* transgene expression primarily in the heart

[redacted]

Study Design

Key Inclusion Criteria

- 18 to 70 years old at the time of signing the informed consent form
- LVEF > 15% and ≤ 45% at screening per local review by ECHO
- Diagnosis of chronic heart failure (HF) for at least 3 months
- New York Heart Association (NYHA) class I/II/III at screening
- Documented heterozygous pathogenic or likely pathogenic mutation in *BAG3*, interpreted according to the American College of Medical Genetics (ACMG) Guidelines, as confirmed by central laboratory

Key Inclusion Criteria cont'd

- On stable HF standard-of-care (SoC) medications for at least 12 weeks prior to Stage 2 consent and during the screening period. If the participant is currently taking diuretics, then diuretics must also be stable for at least 2 weeks prior to Stage 2 consent (minor dose adjustments in diuretics are allowed based on the Investigator's judgment).
- Have medical history of diagnosis of DCM (as per national guidelines)
- Adequate acoustic windows for echocardiography

Key Exclusion Criteria

- Decompensated HF or any cardiopulmonary hospitalization within 4 weeks prior to Stage 2 consent, or during the screening period
- Recipient of any major organ transplant (e.g., heart, lung, liver, bone marrow, renal) or likelihood, in the Investigator's opinion, of undergoing cardiac transplantation, left ventricular assist device (LVAD), or cardiac surgery within 3 months of Stage 2 of screening
- Any of the following within 3 months prior to Stage 2 consent: Acute coronary syndrome, stroke, transient ischemic attack, and cardiac procedures (pacemaker/ICD/CRT-D implantation/coronary artery bypass grafting or percutaneous coronary intervention, coronary revascularization, ablation of atrial fibrillation/flutter, valve repair/replacement, aortic aneurysm surgery, etc.)
- Cardiac ventricular arrhythmia that requires treatment. Participants with atrial fibrillation or flutter and controlled ventricular rate (e.g., resting HR < 110 bpm) are permitted. Participants with cardiac ventricular arrhythmia that are treated with antiarrhythmic agents (e.g., amiodarone) and are stable are permitted.

Key Exclusion Criteria cont'd

- History of untreated clinically significant valve disease
- Clinically significant pericardial disease in the opinion of the Investigator
- Cardiomyopathy attributed to a nongenetic or environmental (including alcohol) cause other than *BAG3* mutation
- Symptomatic bradycardia or second (Mobitz 2) or third-degree heart block without a pacemaker
- History of substance abuse that could contribute to cardiac dysfunction
- Obesity Class 3 or higher (BMI ≥ 40 kg/m^2)
- History of thrombotic microangiopathy (TMA) or coagulopathy

[redacted]

Key Exclusion Criteria cont'd

- Currently on chronic immunosuppression therapy, chronic immunotherapy, or having an immunosuppressive disorder
- Other known factors that would preclude patient from participating in the trial (e.g., liver abnormalities, other comorbidities, etc.)

Other protocol-defined inclusion and exclusion criteria apply.

Patient Referral

For more information, or to refer a patient, please contact:

[ADD CONTACT INFORMATION]

You can also learn more about this study and eligibility at [redacted].com.

[redacted]

[redacted]