

PRESS RELEASE

AnaCardio Announces Phase 1b/2a GOAL-HF1 Results of AC01 Demonstrating Favorable Safety and Sustained Improvements in Cardiac Function on Top of Standard-of-Care Therapy in HFrEF at Late-Breaking Session at HFA 2026

STOCKHOLM, Sweden, May 11, 2026 – AnaCardio today announced detailed results from its Phase 1b/2a GOAL-HF1 study evaluating AC01 in patients with heart failure with reduced ejection fraction (HFrEF), presented in a Late-Breaking Science session at the European Society of Cardiology (ESC) Heart Failure Association (HFA) Congress 2026 in Barcelona, Spain.

The randomized, double-blind, placebo-controlled study demonstrated a favorable safety and tolerability profile, dose-proportional pharmacokinetics with confirmed target engagement, and rapid and sustained improvements in hemodynamics and in cardiac structure and function, including increases in cardiac output and left ventricular ejection fraction, on top of optimized guideline-directed medical therapy.

Late-Breaking Science presentations are reserved for studies of high scientific and clinical importance, reflecting important and timely advances in cardiovascular medicine.

AC01 is a first-in-class, oral ghrelin receptor agonist designed to improve cardiac contractility through enhanced calcium sensitivity.

Key Results from GOAL-HF1

- **Favorable safety and tolerability profile**, with no AC01-related serious adverse events or treatment discontinuations
- **No evidence of tachycardia, sustained arrhythmias, ischemia, or clinically relevant effects on cardiac conduction or blood pressure**
- **Dose-proportional pharmacokinetics and confirmed target engagement**, consistent with the proposed mechanism of action
- **Rapid and sustained improvements in cardiac output**, with increases from baseline of **+29.5% at Day 1 and +22.0% at Day 28** at the 3 mg dose
- **Improvement in left ventricular ejection fraction**, with a mean increase of **+4.8 (SD 1.8) absolute percentage points at Day 28** at the 3 mg dose

Additional exploratory measures of hemodynamics, and cardiac function and structure, showed consistent directional improvements.

“We are highly encouraged by the magnitude, consistency and rapid onset as well as the durability of improvements in cardiac function observed in GOAL-HF1, together with a favorable safety profile,” said Patrik Strömberg, CEO of AnaCardio. *“Heart failure remains a leading cause of death and hospitalization worldwide, and we believe AC01’s differentiated mechanism has the potential to meaningfully improve outcomes for patients. These results represent an important step forward and support the continued advancement of AC01 into Phase 2b clinical development.”*

“These data show that AC01 can improve cardiac output and multiple measures of cardiac structure and function without evidence of tachycardia, arrhythmias, or ischemia,” commented Professor Lars Lund of Karolinska Institutet, and Founder of AnaCardio. “This profile is particularly notable given the historical limitations of traditional inotropic therapies, and suggests that AC01 may represent a novel approach to enhance cardiac contractility while maintaining a favorable safety profile. The consistency of these findings and the absence of typical inotrope-related liabilities support further evaluation in larger clinical studies.”

About the GOAL-HF1 HFrEF study

GOAL-HF1 was a Phase 1b/2a multicenter, randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, pharmacokinetics, and pharmacodynamics of AC01 in patients with heart failure and reduced ejection fraction (HFrEF). All patients had NYHA class II-III heart failure with reduced ejection fraction, an implantable cardioverter-defibrillator (ICD) for primary prevention and were on maximum tolerated guideline-directed medical therapy.

- Phase 1b consisted of a multiple-dose escalation in 32 patients across four sequential dose cohorts (0.3–3 mg), each treated orally twice daily with AC01 or placebo (6+2 in each cohort) for 7 days.
- In Phase 2a, 26 patients were equally randomized into one of three parallel treatment arms and treated orally twice daily with 1 or 3 mg AC01, or placebo for 28 days.

More information about the study is available at www.clinicaltrials.gov (NCT05642507).

About AnaCardio

AnaCardio AB is a privately held clinical stage biopharmaceutical company developing novel drugs to treat heart failure. AnaCardio was founded based on ground-breaking research from Karolinska Institutet showing improved contractility of the heart muscle through a unique and differentiated mechanism. The Company’s lead program AC01, first-in-class calcium-sensitizing contractile agent, is an oral ghrelin mimetic small-molecule, which was in-licensed from Helsinn and is now being developed as a contractile agent in heart failure patients. AnaCardio recently completed a successful Phase 1b/2a study with AC01 that generated proof-of-concept in patients with HFrEF, thus supporting further development of this promising oral, first-in-class drug candidate in patients with advanced heart failure.

Find more information about AnaCardio at www.anacardio.com and follow us on [LinkedIn](#).

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