AnaCardio

PRESS RELEASE

AnaCardio´s Phase 1b/2a GOAL-HF1 study in patients with Heart Failure and Reduced Ejection Fraction (HFrEF) published in *The Lancet*

- Favourable safety profile in marked contrast to traditional inotropic therapeutics
- AC01 showed rapid and sustained numerical improvements in cardiac output, structure and function

STOCKHOLM, Sweden, June 25, 2026 – AnaCardio, a clinical stage biopharmaceutical company developing novel drugs to treat heart failure, today announced the publication in *The Lancet* of results from its Phase 1b/2a GOAL-HF1 study evaluating AC01, a first-in-class, oral calcium-sensitising contractile agent, in patients with heart failure with reduced ejection fraction (HFrEF). The results showed a favourable safety and tolerability profile, dose-proportional pharmacokinetics with confirmed target engagement. In exploratory efficacy analyses, numerical rapid and sustained improvements in haemodynamics and cardiac structure and function were observed on top of optimised guideline-directed medical therapy (GDMT).

Heart failure remains a leading cause of death and hospitalisation worldwide. No safe oral therapy that improves cardiac contractility has been approved to date and, historically, development efforts in this area have been limited by safety concerns and by a lack of meaningful improvement in clinical outcomes. AC01 has a novel, unique mode of action. Publication in *The Lancet* represents rigorous independent peer-reviewed recognition of the scientific and clinical relevance of the GOAL-HF1 data, underscoring both the distinctiveness of AC01 and the strength of the GOAL-HF1 results.

"Publication of the GOAL-HF1 results in The Lancet is a defining milestone for AnaCardio and represents the highest level of scientific validation we could receive for AC01. The data confirm what we have consistently seen across preclinical and clinical studies to date: AC01 improves cardiac function with a clearly differentiated safety profile, and demonstrates significant potential as a chronic treatment in HFrEF patients. Heart failure remains a leading cause of death and hospitalisation worldwide, and we believe these results represent an important step forward and support the rapid advancement of AC01 into Phase 2b clinical development," said Patrik Strömberg, CEO of AnaCardio.

These findings reinforce AnaCardio's confidence in AC01 as a first-in-class, oral calcium-sensitising contractile agent with a differentiated mechanism, and support rapid advancement into Phase 2b clinical development.

Key Results from GOAL-HF1

- **AC01 appeared safe and well tolerated**, with no AC01-related serious adverse events, no deaths, and no treatment discontinuations due to adverse events
- **No apparent signs of tachycardia, new onset tachyarrhythmias, myocardial ischemia, morphological or conduction abnormalities and no case of symptomatic hypotension**
- **Rapid improvements in cardiac output and stroke volume — core measures of the heart's pumping capacity — observed from Day 1 and sustained through Day 28**, consistent with a direct effect on cardiac contractility
- **Improvement in left ventricular ejection fraction**, with a mean increase of **+4.8 absolute percentage points at Day 28** in the 3 mg group versus +1.6 percentage points in placebo

"The exploratory efficacy results from GOAL-HF1 are very encouraging, with AC01 showing improvements in cardiac output and multiple measures of cardiac structure and function. Importantly, the drug was safe and well tolerated, with no evidence of tachycardia, arrhythmias, or ischemia — a profile that stands in marked contrast to the historical limitations of traditional inotropic therapies. Taken together, these findings provide a strong foundation to guide late-stage clinical trials, and hold real promise to translate into meaningful benefits for patients in terms of mortality, morbidity, and quality of life," commented Professor Lars Lund, Cardiologist at Karolinska University Hospital and Founder of AnaCardio.

About the GOAL-HF1 HFrEF study

GOAL-HF1 was a Phase 1b/2a multicentre, randomised, double-blind, placebo-controlled study evaluating the safety, tolerability, pharmacokinetics, and pharmacodynamics of AC01 in 58 patients with HFrEF across 14 sites in the Netherlands, United Kingdom, Sweden, and Italy. All patients had NYHA class II–III HFrEF (mean ejection fraction 31.4%), a transvenous implantable cardioverter-defibrillator (ICD) for primary prevention, and were on maximum tolerated guideline-directed medical therapy. Phase 1b consisted of multiple ascending dose escalation in 32 patients across four sequential dose cohorts (0.1–3 mg twice daily, 7 days). In Phase 2a, 26 patients were equally randomised to 1 mg AC01, 3 mg AC01, or placebo orally twice daily for 28 days. More information about the study is available at www.clinicaltrials.gov (NCT05642507).

The publication, "Safety, pharmacokinetics, and exploratory efficacy of the oral ghrelin receptor agonist AC01 in heart failure with reduced ejection fraction (GOAL-HF1): a randomised, double-blind, placebo-controlled, phase 1b/2a study", is available in The Lancet.

About AnaCardio and AC01

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, a first-in-class oral calcium-sensitising contractile agent, is a ghrelin mimetic small-molecule that was in-licensed from Helsinn and is now being developed in heart failure patients. With proof-of-concept now published in *The Lancet* and positive scientific advice received from the FDA and EMA establishing a favourable development path, AnaCardio is advancing AC01 into Phase 2b clinical development. The company has raised over USD 40 million to date. AnaCardio is based in Stockholm, Sweden.

Find more information about AnaCardio at www.anacardio.com and follow us on LinkedIn.

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