PRESS RELEASE

AnaCardio reports first patient dosed in the phase 2a study evaluating AC01 in patients with heart failure and reduced ejection fraction (HFrEF)

February 25, 2025, Stockholm, Sweden - AnaCardio, a clinical-stage biopharmaceutical company developing novel contractile agents to treat patients with heart failure today announced that the first patient has been dosed in the phase 2a part of the GOAL-HF1 study evaluating AC01 in patients with HFrEF. AC01 is a novel, selective oral ghrelin receptor (GHSR1a) agonist, in development to improve contractility in patients with heart failure.

The phase 2a part of the GOAL-HF1 study is a randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of AC01 following 28 days treatment in patients with HFrEF. The study has been designed in collaboration with a panel of senior heart failure experts and is being conducted at 13 highly specialized heart failure centers in Sweden, the Netherlands, Italy and the UK. Study results are expected by the end of the year.

"We are very excited to dose the first patient in this phase 2a study with AC01, a new, promising therapeutic option with potential to improve outcomes for patients with chronic advanced HFrEF. This study will help us better understand the benefits and risks over time and establish clinical proof-of-concept for this novel treatment", said Professor Mark Petrie at the Royal Infirmary Hospital in Glasgow.

"After successfully completing the multiple-ascending-dose part of the GOAL-HF1 study, achieving full target engagement within a safe dose range, we are now thrilled to expand the evaluation of AC01 to a 4-week Randomized Clinical Trial with a broader set of exploratory efficacy endpoints and a growing team of study sites", said Elin Rosendahl, Chief Development Officer at AnaCardio.

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, a first-in-class calcium sensitizing inotrope, 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. The company has raised over USD 35 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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About the GOAL-HF1 HFrEF study

The GOAL-HF1 study is 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 with reduced ejection fraction (HFrEF). The first part of GOAL-HF1 included a phase 1b multiple-dose-escalation, in a total of 32 patients, 8 in each of 4 sequential dose cohorts. Patients were treated orally, twice daily with ascending doses of AC01 (0.3 to 3.0 mg) or placebo for 7 days; all patients completed the study according to plan. All patients had New York Heart Association (NYHA) class II or III, an ICD for primary prevention and were treated with optimal guideline-based medical therapy for HFrEF. In the second part of the study (phase 2a, cohort expansion), up to 30 patients will be randomized into 3 treatment groups and treated for 28 days at dose levels identified on the basis of the completed phase 1b part. More information about the study is available at www.clinicaltrials.gov (NCT05642507).

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