PRESS RELEASE

AnaCardio announces positive scientific advice from the FDA and EMA, establishing a favourable development path for AC01 treatment of chronic HFrEF

- ***Alignment reached with both the FDA and EMA on key elements of the AC01 development strategy in chronic HFrEF, allowing for a lean, straightforward and coherent plan across both Europe and the USA***
- ***AC01, a novel, selective oral ghrelin receptor (GHSR1a) agonist, is currently in Phase IIa (GOAL-HF1) and the advice will enable the planned Phase IIb study to satisfy both the FDA and EMA recommendations***

Stockholm, Sweden, July 17, 2025 - AnaCardio, a clinical-stage biopharmaceutical company developing novel contractile agents to treat patients with heart failure today announces positive scientific advice from both the US Food and Drug Administration (FDA) and the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on the overall development strategy for AC01, the company's selective oral ghrelin receptor (GHSR1a) agonist, as a novel treatment of chronic heart failure with reduced ejection fraction (HFrEF).

In March/April 2025, AnaCardio requested a Type B meeting with FDA and Scientific Advice from the EMA CHMP to obtain agreement on the acceptability of the proposed CMC, non-clinical and clinical programs to support a potential future New Drug Application (NDA) and Marketing Authorization Application (MAA), respectively, and in particular of the design of the planned Phase IIb study in HFrEF patients.

The guidance provided was well aligned across agencies and supports a lean and straightforward development path to satisfy both the FDA and EMA recommendations. With the advice provided on the Phase IIb study, AnaCardio is now optimizing the plan and continuing preparations for initiation of the Phase IIb study during 2026, following the readout of the ongoing GOAL-HF1 study.

Patrik Strömberg, CEO, commented: *"The favorable and well aligned opinions from the two regulatory agencies allow us to accelerate the combined clinical development program in these major territories. We are thrilled at the encouraging progress to date, as our company addresses a major unmet need for patients living with HFrEF".*

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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 40 million to date. AnaCardio is based in Stockholm, Sweden.

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

About the GOAL-HF1 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 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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