PRESS RELEASE

AnaCardio Announces Completion of Target Enrollment in Phase 2a Study of AC01 in Heart Failure; Results Expected Year-end 2025

Stockholm, Sweden, September 16, 2025 – AnaCardio, a clinical-stage biopharmaceutical company developing novel contractile agents for heart failure, today announced that its ongoing Phase 2a study of AC01 in patients with heart failure and reduced ejection fraction (HFrEF) is fully enrolled and remains on track to report results by year-end 2025.

In the Phase 2a part of the GOAL-HF1 study, a total of 26 patients were randomized to receive AC01 or placebo for 28 days at dose levels identified from the previously completed Phase 1b part, which dosed patients over 7 days. 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.

"*We are delighted to have reached full enrollment in this important study of AC01*," said Professor Roy Gardner, Principal Investigator at The Golden Jubilee National Hospital, Glasgow, UK. *"This milestone brings us closer to understanding the clinical potential of this first-in-class therapy for patients with HFrEF. We eagerly look forward to the results, which could represent a significant step toward improving outcomes for this large, underserved patient population."*

"Completing the target enrollment on schedule in the Phase 2a study part is an important achievement for AnaCardio and demonstrates great execution by our team and partners," said Elin Rosendahl, Chief Development Officer at AnaCardio*. "We are excited to advance AC01 through this critical stage of development, with data expected later this year. With AC01's novel mechanism and encouraging clinical profile to date, we believe it has the potential to transform the treatment paradigm in patients with HFrEF."*

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).

In the Phase 1b study part, a total of 32 patients, 8 in each of 4 sequential dose cohorts 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 and full target engagement was achieved within a safe dose range.

In the Phase 2a study part, 24 to 30 patients were planned to be enrolled and equally randomized into 1 of 3 parallel treatment arms and given AC01 or placebo twice daily for 28 days.

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

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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.

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