

AnaCardio reports first patient dosed in the GOAL-HF1 study, a Phase 1b/2a Clinical Study in Heart Failure with AC01 in the EU and UK

Solna, Sweden and Lugano, Switzerland, April 13, 2022 - AnaCardio, a Swedish clinical-stage biopharmaceutical company focussed on developing novel contractile agents with a unique mode-of-action based on the ghrelin signaling pathway, today announced that the first patient has been successfully dosed in its GOAL-HF1 study of AC01 in patients with heart failure and reduced ejection fraction (HFrEF). AnaCardio licensed AC01, an oral ghrelin peptidomimetic small-molecule, from Helsinn Group in February 2022.

As previously announced, 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). AnaCardio has received approval from the Competent Authorities and Ethics committees in Sweden, the Netherlands, Italy and the UK for the GOAL-HF1 trial. GOAL-HF1 includes two parts: a dose escalation phase and cohort expansion phase. The study has been designed in collaboration with a panel of senior heart failure experts and is being conducted at highly specialized heart failure centres in Europe with a view of establishing proof-of-concept to allow confirmatory later stage studies. The pharmacodynamic endpoints include methods to measure cardiac function noninvasively as well as a range of mechanistic wet biomarkers of target modulation.

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

Dr Tonje Thorvaldsen, Principal Investigator Karolinska University Hospital, Stockholm commented: “We’re enthusiastic to be starting this much awaited trial aimed to provide proof-of-concept for AC01 as a novel contractile agent intended for heart failure patients with reduced ejection fraction.”

“Dosing the first patient in the GOAL-HF1 trial is an important milestone for the AC01 programme,” **said, Dr. Melanie Rolli, Helsinn Group CEO.** “We are excited to see the significant advancements made by our partner and licensee AnaCardio in developing this potentially first-in-class treatment to improve contractility and disease outcomes for heart failure patients.”

“The GOAL-HF1 study is an important trial to investigate safety and tolerability, PK/PD ultimately to generate Proof-of-Concept for AC01 and its novel mode-of-action as a contractile agent in HFrEF patients, leveraging the strong preclinical data for this molecule as well as clinical data with ghrelin peptide in patients”, **commented Patrik Strömberg, CEO of AnaCardio.**

About Helsinn

Helsinn is a fully integrated global biopharma company headquartered in Lugano, Switzerland. It is focused on improving the lives of cancer patients all over the world with a leading position in cancer supportive care and a focus on cancer therapeutics and rare diseases.

Helsinn is a third-generation family-owned company, that since 1976 has been focused on improving the lives of patients, guided by core values of respect, integrity and quality. Helsinn’s unique business model enables it to in-license or acquire assets at a late stage of development.

It has a commercial presence in 190 countries either directly, with operating subsidiaries in the U.S. and China, or via its network of long-standing trusted partners. Helsinn also has a fully integrated supply chain and product development through its subsidiary in Ireland, Helsinn Birex Pharmaceuticals Ltd.

Helsinn plays an active and central role in promoting social transformation in favor of people and the environment. Sustainability is at the heart of everything we do, which is reinforced in the company’s strategic plan by a commitment to sustainable growth.

To learn more about Helsinn please visit: www.helsinn.com

About AnaCardio

AnaCardio AB is a privately held Swedish, 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. Its lead program AC01 is an oral ghrelin peptidomimetic small-molecule is being developed as a contractile agent in heart failure patients.

You can find more information about AnaCardio at www.anacardio.com.

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