AnaCardio

PRESS RELEASE

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AnaCardio Receives Regulatory Approval to Start a Phase 1b/2a Clinical Study in Heart Failure with AC01 in the EU and UK

AnaCardio today announces approval for the GOAL-HF1 Phase 1b/2a study from the competent authorities and ethics committes in Sweden, The Netherlands, Italy and the United Kingdom. This 28-day study will evaluate the effects of orally administered AC01 on safety, tolerability, pharmacokinetics and a series of pharmacodynamic readouts in patients with heart failure with reduced ejection fraction (HFrEF). The study was submitted for approval in EU under the Clinical Trial Regulation (CTR), making it one of the first studies to be approved under the new EU procedures. The first patients are planned to be enrolled within the next few months. The GOAL-HF-1 study will be performed in collaboration with Worldwide Clinical Trials (Worldwide). Worldwide is a leading global, midsize contract research organization (CRO) that provides top-performing bioanalytical and Phase 1-4 clinical development services to the biotechnology and pharmaceutical industries, with cardiovascular as one of its core therapeutic focus areas.

AnaCardio is developing novel contractile agents with a unique mode-of-action based on the ghrelin signalling pathway, intended to increase contractility without causing adverse tachycardia, arrhythmia, ischemia, or hypotension. AnaCardio´s lead candidate AC01 is an oral ghrelin peptidomimetic small-molecule that in preclinical studies increases contractility/force and sensitizes cardiac cells to calcium, as opposed to conventional inotropes that increase calcium concentrations and flux. The latter may cause life-threatening arrythmias and cardiac ischemia, underlining the need for the development of novel, safe contractile agents for these patients.

"It is with great excitement that we are finalizing preparations to start the GOAL-HF1 clinical trial with AC01 in patients with HFrEF across Europe," says Allan Gordon, Chief Medical Officer at AnaCardio. *"This study will provide us with valuable clinical information, both with regard to safety and tolerability, PK/PD and initial signs of clinical benefit, and with the hope to take this small molecule to Proof-of-Concept. AC01 is addressing the underlying disease in HFrEF, namely reduced contractility and pump dysfunction and has the potential to be the first oral safe contractile agent,"* continued Allan Gordon.

Peter Benton, President and Co-CEO at Worldwide added: *"We are pleased to be part of this innovative, milestone study with AnaCardio. Together with the AnaCardio team, we have successfully navigated the new EU procedure with GOAL-HF1 marking one of Worldwide's first studies submitted and approved under the Clinical Trial Regulation (CTR). This important study is a testament to AnaCardio's mission to develop novel drugs to treat heart failure and improve the lives of patients – something we are especially passionate about at Worldwide."*

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 planned to enter clinical development in heart failure patients in 2022.

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

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