

PRESS RELEASE

Stockholm, Sweden, August 17, 2023

AnaCardio receives IND approval from the FDA for AC01 to Start a Clinical Pharmacology Study

AnaCardio, a Swedish clinical-stage biopharmaceutical company focussing on developing novel contractile agents to treat patients with heart failure, today announced that the U.S. Food and Drug Administration (FDA) has granted the company's Investigational New Drug (IND) application for the investigational drug AC01. The approval enables expansion of the clinical development program for AC01 to the US, and to initiate a study in healthy volunteers. This study will evaluate the effects of food on the pharmacokinetics of orally administered AC01, and will provide important data to inform design of subsequent studies in heart failure patients.

AnaCardio is developing novel therapeutic molecules with a unique mode-of-action based on the ghrelin signalling pathway, aimed at safely increasing contractility in patients with heart failure and reduced ejection fraction (HFrEF). AnaCardio's lead candidate AC01 is an oral ghrelin peptidomimetic small-molecule that is now being tested in an ongoing phase 1b/2a study in HFrEF patients in Europe.

"The U.S. Food and Drug Administration's approval of our IND application is an important milestone and a recognition of the validity and robustness of the preclinical and clinical data generated for AC01 so far, and helps accelerate our clinical programme towards later stage clinical trials aimed at demonstrating clinical benefit of AC01 in HFrEF patients.", commented Göran Westerberg, Head of Clinical and Regulatory Affairs at AnaCardio.

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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