

Karolinska Development's portfolio company AnaCardio presents positive top-line data from the phase 2a study of its drug candidate AC01

STOCKHOLM, SWEDEN December 10, 2025. Karolinska Development AB (Nasdaq Stockholm: KDEV) today announces that its portfolio company AnaCardio has reported strong, positive results from the phase 2a clinical trial GOAL-HF1, evaluating the drug candidate AC01 in patients with heart failure and reduced ejection fraction (HFrEF). The study met its primary endpoint, demonstrating a favorable safety and tolerability profile, and showed encouraging, consistent efficacy signals paving the way for a rapid advancement to phase 2b.

AnaCardio AB is a privately held Swedish clinical-stage biopharmaceutical company developing novel drugs to treat heart failure. The company has recently concluded a clinical phase 2a study with its lead asset, AC01, demonstrating a favorable safety and tolerability profile, which was the study's primary endpoint.

While the study was not powered for placebo-controlled efficacy evaluation, exploratory efficacy assessments showed encouraging, consistent signals of rapid and sustained improvements in haemodynamics and cardiac structure and function over 28 days of treatment. The study enrolled 26 patients across 13 European heart failure centers, randomized to receive 1 mg or 3 mg AC01, or placebo twice daily for 28 days.

The pharmacokinetics of AC01 were predictable and dose-proportional, and target engagement was confirmed by a dose-dependent increase in growth hormone release, consistent with previous data for the drug candidate.

No treatment-emergent adverse events leading to discontinuation or drug-related serious adverse events were found in the study, nor any evidence of ischemia, new onset of sustained arrhythmias, morphological or conduction abnormalities, or clinically relevant effects of AC01 on blood pressure. AnaCardio aims to initiate the phase 2b study in mid-2026

"These strong data confirm our solid belief in the potential of AC01 to be a game-changer for the treatment of heart failure. A favorable safety and tolerability profile, together with promising efficacy signals, provides a robust base for the continued clinical evaluation," says Viktor Drvota, CEO of Karolinska Development.

Karolinska Development's ownership in AnaCardio amounts to 10 percent.

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TO THE EDITORS



About Karolinska Development AB

Karolinska Development AB (Nasdaq Stockholm: KDEV) is a Nordic life sciences investment company. The company focuses on identifying breakthrough medical innovations in the Nordic region that are developed by entrepreneurs and leadership teams. The Company invests in the creation and growth of companies that advance these assets into commercial products that are designed to make a difference to patients' lives while providing an attractive return on investment to shareholders.

Karolinska Development has access to world-class medical innovations at the Karolinska Institutet and other leading universities and research institutes in the Nordic region. The Company aims to build companies around scientists who are leaders in their fields, supported by experienced management teams and advisers, and co-funded by specialist international investors, to provide the greatest chance of success.

Karolinska Development has a portfolio of eleven companies targeting opportunities in innovative treatment for life-threatening or serious debilitating diseases.

The Company is led by an entrepreneurial team of investment professionals with a proven track record as company builders and with access to a strong global network.

For more information, please visit www.karolinskadevelopment.com.