



Press release

Malmö, January 9, 2018

DAN-NICADII study to expand the applicability of the non-invasive Acarix CADScor® System for rapid ruling out Coronary Artery Disease

Handheld system rules out coronary arterial stenosis, saving valuable time in frontline triage and avoiding the need for expensive diagnostics.

Acarix AB (publ) ("Acarix" or the "Company") announced the initiation of a multi-center trial of its handheld CADScor® System for non-invasive, non-radiation acoustic detection of Coronary Artery Disease ("CAD"). The results from the extensive study are expected to be available early 2020. Acarix believes the device has the potential to both greatly improve triaging of patients and reduce the need for costly further invasive diagnostic investigations. The new study is intended to further support the eligibility, document the positive effects on health economics and also expand the applicability to patients 30-39 years of age. Estimated market for frontline CAD diagnostics is 100 MEUR in Germany alone with an option to expand the market further.

The CADScor® System combines ultra-sensitive phonocardiography to detect turbulent arterial flow and myocardial movement in a handheld device to provide a patient specific CAD-score in less than 8 minutes. The Principal Investigator is Morten Böttcher, MD PhD FESC, Department of Cardiology, Aarhus University Hospital, Denmark concluded: *"The acoustic-based recording device, the CADScor® System, enables improved risk stratification in suspected CAD patients. With a negative predictive value of 96%, this new acoustic rule-out system could potentially supplement clinical assessment to guide decisions on the need for further investigation and thereby reduce the demand for more advanced, costly and invasive diagnostic modalities."* The trial results are expected to involve 1,500-2,000 patients with a low-to-intermediate likelihood of CAD from four Danish hospitals.

The study results are expected to improve on the negative predictive value of 96% which suggests using the CADScor® System as a first-line CAD rule-out method; thus, avoiding expensive and/or invasive diagnostic modalities for many of those patients.

Today, patients are referred for CAD evaluation by Cardiac Computed Tomography Angiogram (CTA) which involves injection of contrast media and X-ray exposure. Using the non-invasive and risk-free CADScor® System, features from the audiogram is automatically combined with clinical risk factors (e.g. gender, age and hypertension) to provide a CAD-score, which correlates with the CAD risk.

Acarix CEO Søren Rysholt Christiansen commented:

"The existing data already show that the CADScor® System quickly and cost-effectively can provide answers to the pressing issues in CAD diagnosis. Coronary Artery Disease affects more than 120 million people worldwide, but the current diagnostic pathway, which can rapidly escalate to expensive imaging and invasive coronary angiography, can be improved and patient anxiety can be reduced. With the DAN-NICADII study we expect to gather performance and economic data supporting the CADScor® System as a fast and safe frontline assessment to reduce patient referrals by approximately 50% – a win-win for patients, payers and physicians."

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Notes to editors:Acarix, CADScor®System and cardiac sound measurement

Acarix was established in 2009 and is listed on Nasdaq First North Premier. Acarix's CADScor®System uses an advanced sensor placed on the skin above the heart to listen to the sounds of cardiac contraction movement and turbulent flow. It has been designed to be an all-in-one system in the sense that the heart signal will be recorded, processed, and displayed as a patient specific score, the CAD-score, on the device screen. Readings are obtained in less than 8 minutes. Safe and suitable for use in both out- and inpatient settings, the CADScor®System thus has the potential to play a major role in patient triage, avoiding the need for many patients to undergo stressful invasive diagnostic procedures.

See more at www.acarix.com.

Press photos: <http://www.acarix.com/about-us/press-downloads/press-photos/>

Recently published study: <http://heart.bmj.com/content/early/2017/11/09/heartjnl-2017-311944>