Press release

Malmö March 17, 2017

Acarix CADScor®System multi-center trial results confirms previous preliminary results of CADScor®System ruling out CAD with 97% negative predictive value

Acarix AB (publ) ("Acarix" or the "Company") today announced the results from a new multi-center trial of its handheld CADScor®System for non-invasive, non-radiation acoustic detection of Coronary Artery Disease ("CAD"). The results are presented at the American College of Cardiology 2017 Annual Scientific Meeting held in Washington on 17-19 March 2017 and showed that the handheld CADScor®System rules out CAD with 97% negative predictive value. The results confirm the Company's previously announced figures which, prior to this study, was unconfirmed.

The trial involved 1,675 patients from two Danish hospitals with a low to intermediate likelihood of CAD referred for Cardiac CTA and showed that the handheld CADScor®System rules out CAD with 97 % negative predictive value. Acarix believes this opens the possibility of use as a frontline test, reducing patient anxiety and waiting times, as well as improving triage for patients needing more expensive and invasive diagnostic modalities.

The CADScor®System combines acoustic detection of turbulent arterial flow and myocardial movement with advanced algorithms in a handheld device to provide a patient specific CAD-score in less than 10 minutes. The research was led by Principal Investigator Morten Böttcher, MD PhD FESC and by Simon Winther, MD PhD, Department of Cardiology, Aarhus University Hospital, Denmark:

"*Despite the availability of improved risk stratification algorithms, the incidence of normal investigations such as nuclear or CT imaging remains high. We therefore tested the diagnostic accuracy of the CADScor®System for ruling out CAD to see if it could be used to reduce demand for more advanced diagnostic modalities. We have concluded that, with its ability to rule out CAD with a 97% negative predictive value, this advanced, easy to use, stethoscope like device could indeed be deployed as a frontline test*."

A CAD-score was recorded in all 1,675 patients enrolled in the trial, with the CAD-score algorithm including both acoustic features and clinical risk factors (gender, age and hypertension). Low risk was indicated by a CAD-score value less or equal to 20. The algorithm CAD-score version 3 was developed using recordings from 711 patients from previous studies and a training cohort of 589 patients from the present study. The remaining 1086 patients were used as the validation cohort. The CAD-score was successfully analyzed in 1464 (87%) patients. Hemodynamic significant CAD was present in 134 (9.3%) patients. There were no differences in the performance of the CAD-score algorithm in the training vs. validation cohorts. In the entire cohort, the CAD-score differed between coronary artery calcium score (CACS) groups CACS=0 (n=745), CACS 1-400 (n=550) and CACS more than 400 (n=142); CAD-score: 17 ±11, 24 ±12, and 30 ±12 (p less than 0.001). CAD-score was also significant lower for patients without vs. with hemodynamic significant stenosis 20 ±12 vs 30 ±12 (p less than 0.001). Diagnostic performance evaluated by receiver operating characteristic curve showed an accuracy of: 72% (CI: 67% - 77%). CAD-score cut-off less or equal to 20 had an accuracy of:

• Sensitivity: 81% (CI: 74% to 88%)
• Specificity: 53% (CI: 50% to 56%)
• PPV: 15% (CI: 13% to 18%)
• NPV: 97% (CI:95% to 98%)

Acarix CEO Søren Rysholt Christiansen commented:

"*We are delighted with the results of the trial. Coronary Artery Disease affects more than 120 million people worldwide but the current diagnostic pathway, which can rapidly escalate to expensive imaging and coronary angiography, is inefficient. For example, a recent Danish study showed that more than 90% of patients presenting with chest pain symptoms to their general practitioner do not have CAD. If adopted, the CADScor®System can provide rapid frontline assessment which could translate into a potential reduction in patient referrals by approximately 50%. – a win-win for patients, payers and physicians.*"

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This information is information that Acarix AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation 596/2014. The information was submitted for publication, through the agency of the contact person set out above, at 15:00 CET on 17 March 2017.

Notes to editors:

Acarix , CADScor®System and cardiac sound measurement
Acarix A/S was established in 2009, and since 2010 investors SEED Capital (DK) and Sunstone Life Science Ventures (DK) have supported it towards market introduction. Acarix has attracted a highly-experienced management team who have held senior positions in international medical device companies - CEO Søren Rysholt Christiansen with ELOS Medtech, GN ReSound and Cook Medical.

Acarix's CADScor®System is based on engineering excellence in sound recording and signal processing. It has long been known that both cardiac contraction movement and turbulent flow can generate sound. Contraction related sounds are in lower frequency, whereas turbulent sounds in the streaming blood caused by partial obstruction (stenosis) in the coronary arteries are of higher frequencies. The detection of these murmurs is delicate, since the energy of the murmurs is very weak. Detecting and recording the coronary murmurs requires not only an advanced sensor but also means for proper attachment to the skin above the heart to optimize the recorded signal and to avoid external noise.

The Acarix CADScor®System 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. The CADScor®System contains the necessary electronics to instruct professionals during use and to guide through the recording periods. The system also contains a docking station for daily qualification of the sensor. Further the system integrates with an adhesive patch for locking the CADScor® sensor to a fixed position above the heart during the recording.

The software embedded in The Acarix CADScor®System ensures that adequate recording conditions are controlled at every examination.

The CADScor®System is CE Marked (by TÜV in 2015) and due for commercial launch in 2017.

See more at www.acarix.com