

Press release

Malmö, June 13, 2017

Acarix Receives First Commercial Order For CADScor® System For Early Detection Of Coronary Artery Disease From Danish Hospital

Commercialization program on track

Acarix AB (publ) (“Acarix” or the “Company”) today announced that Herning Hospital has placed the first commercial order for the CADScor® System for non-invasive, non-radiation acoustic detection of Coronary Artery Disease (CAD). Researchers at the hospital have extensively trialed CADScor® System and recently presented data at the American College of Cardiology 2017 Annual Scientific Meeting showing that CADScor® System rules out CAD with 97% negative predictive value. The timing of this first order is a sign of the success of Acarix’s commercial development following an oversubscribed IPO on Nasdaq First North Premier in Stockholm in late 2016. Currently the company is talking to a number of other potential customers in Germany and Scandinavia.

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 decision to purchase CADScor® System was explained by Morten Bøttcher, MD PhD FESC, head of the Cardiac Imaging center at the Hospital Unit West in Denmark and associate professor at Aarhus University: *“Despite the availability of improved risk stratification algorithms, the incidence of normal investigations such as nuclear or CT imaging remains high. We were therefore interested in testing 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 device could indeed have the potential to be deployed as a routine frontline test. We now look forward to explore the performance of the device in routine clinical use.”*

The research carried out by Dr. Bøttcher’s team involved recording a CAD-score in 1,675 patients. Low risk was indicated by a CAD-score value at or below 20. Diagnostic performance evaluated by a receiver operating characteristic curve showed an accuracy of: 72% (CI: 67% - 77%). CAD-score cut-off at or below 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: *“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. We are very pleased that having thoroughly evaluated the CADScor® System, Herning Hospital will become our first commercial customer. Dr. Bøttcher and his team have an international reputation for outstanding research in the area of Coronary Artery Disease and we look forward to continuing our close collaboration with them.*

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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.

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

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