Press release (MAR)
Malmö, Sweden, November 26, 2020

FDA identifies exclusive code for the CADScor®

After yesterday's announcement and further analysis of the FDA approval, Acarix AB today announce that the company's marketing approval of the CADScor®System in the US was granted under a new generic type of code and device segment by the US Food and Drug Administration (FDA). The code covers *Coronary artery disease risk indicator using acoustic heart signals*. Acarix is the sole company in the market that has been granted this label.

In the approval letter from the FDA, CADScor® is defined as "…a *Coronary artery disease risk indicator using acoustic heart signals,* a device that records heart sounds including murmurs and vibrations to calculate a patient-specific risk of presence of coronary artery disease, as an aid in cardiac analysis and diagnosis.

"We are the only company to have this label. This is an opportunity allowing us to create a new segment and, in collaboration with clinicians, define the market and clinical standards in the US Per Persson, CEO of Acarix.

"With the approved intended use and new code, we can now accelerate commercial preparations regarding the reimbursement process and potential commercial partner." says Per Persson.

For further information, please contact:
Per Persson, CEO, E-mail: per.persson@acarix.com, Phone: +46 73 600 59 90

The information disclosed above is mandatory for Acarix AB (publ) to publish pursuant to the EU Market Abuse Regulation. This information was submitted for publication through the agency of the above contact person on November 26, 2020 at 14:20 am (CET).

About Acarix:
Acarix was established in 2009 and is listed on Nasdaq First North Premier Growth Market (ticker: ACARIX). 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. Readout is obtained in less than 10 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. Redeye AB (+46 (0)8 121 576 90, certifiedadviser@redeye.se) is Certified Adviser to Acarix. For more information, please visit www.acarix.com.