Press release

Malmö, Sweden 16 December, 2019

Acarix submits FDA application

Acarix AB (publ) (ACARIX: FN Stockholm) today announced the submission of a De Novo application to the American Food and Drug Administration (FDA) for the CADScor® System in preparation of a US market entry. The company is now cautiously initiating preparations for market launch.

Acarix has filed a De Novo application as there is no predicate device with a comparable indication in the US market. The US is the world's largest med tech market and the innovative CADScor technology is well fit for the US healthcare system and demographics.

"Using the De Novo pathway strengthens our future position in the US as the CADScor is likely to lead the market development in this segment. In parallel with the application we are planning commercial activities with an observant eye on the timing of the FDA process. We want to be ready for market approval, but we also need to balance our activities." said Per Persson, CEO of Acarix.

Acarix' De Novo application format has been accepted by the FDA and the classification review has been passed. The FDA review is now in progress and as for all De Novo applications, FDA's ambition is to share its initial feedback within 150 days. The duration of the process is however hard to predict as the review process is dependent on FDA's comments on the application and if the FDA requests additional information.

For further information, please contact:

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Acarix is listed on Nasdaq First North Growth Market in Stockholm.
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The information was released for public disclosure, through the agency of the contact person above, on December 16, 2019 at 10.00 (CET).

About Acarix:
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. 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. Wildeco Ekonomisk Information AB is the company's Certified Adviser. For more information please visit www.acarix.com.