Press release (MAR)
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FDA requests supplementary information for Acarix breakthrough designation request for heart failure diagnosis

The Food and Drug Administration (FDA) has requested supplementary information in reviewing the breakthrough designation request from Acarix for its innovative AI-based technology for heart failure diagnosis in USA.

"We appreciate the diligence and feedback by FDA regarding the review of our application for breakthrough designation for our AI-based diagnostic technology for heart failure. The team is now prioritizing the work based on the concrete proposals for supplementation we have received so that we can respond to the FDA as soon as possible. Our goal is to expand our AI-based technology to also include heart failure, where rapid access to diagnostic information also can guide optimal patient care and yield improved clinical outcomes faster" says Helen Ljungdahl Round, CEO.

The new Acarix Seismo System is an AI-powered, non-invasive method that offers a simple, rapid risk assessment for patients with suspected heart failure in less than 10 minutes. Acarix breakthrough application is based on clinical data generated from the Seismo study performed in Denmark.

Heart failure affects more than 6 million people in the USA at costs exceeding $30 billion per year. It is a progressive condition that worsens over time, if left untreated. Treatment options depend on the stage of heart failure, from lifestyle changes and medications in the early stages to implantation of cardiac devices and medications in later stages. The availability of a rapid and cost-effective diagnostic tool to help quickly guide early intervention has significant potential to improve clinical outcomes of heart failure. Acarix intends to strengthen its leading position using AI based technology in cardiac care and patient management.

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About Acarix:
Acarix is a Swedish medical device company that innovates solutions for rapid AI-based rule out of Coronary Artery Disease (CAD). The CE approved and FDA DeNovo cleared Acarix CADScor®System is intended for patients experiencing chest pain with suspected CAD and designed to help reduce millions of unnecessary, invasive and costly diagnostic procedures. The CADScor®System calculates a patient-specific CAD-score non-invasively in less than 10 minutes and can help rule out more than

one third of patients with at least 96% certainty (in a population with approx. 10% CAD prevalence). Acarix is listed on the Nasdaq First North Premier Growth Market (ticker: ACARIX). Redeye AB (+46 (0)8 121 576 90, certifiedadviser@redeye.se) is Certified Advisor of Acarix. For more information, please visit www.acarix.com.