Press release
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Acarix submits breakthrough designation request with FDA for heart failure diagnosis

Acarix expands its portfolio and submits a breakthrough designation request for its innovative technology for heart failure diagnosis with the Food and Drug Administration (FDA) in USA.

Heart failure affects more than 6 million people in the USA at costs exceeding $30 billion per year. Yet millions remain undiagnosed and early detection is critical. 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.

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

"I am very proud of this FDA submission, and we believe the Seismo System has the potential to radically improve early diagnosis of heart failure. The Seismo System provides AI-based rapid access to diagnostics information, which can help better guide optimal patient care and yield improved clinical outcomes faster. We are expecting a response from FDA in April." says Helen Ljungdahl Round, CEO.

Heart failure 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.

With this FDA breakthrough submission, Acarix intends to strengthen its leading position using AI based technology in cardiac care and patient management.

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The information was provided, through the agency of the above contact person, for publication at the time specified by the company's news distributor, GlobeNewswire.

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.