



Acarix Provides Update on RHTP and Saudi Arabia Regulatory Process

Acarix has received several inquiries from shareholders regarding the status of the U.S. Rural Health Transformation Program (RHTP) and regulatory approval in the Kingdom of Saudi Arabia (KSA) and would like to provide a brief update.

Both initiatives continue to progress, although the timing and final decisions remain outside of Acarix's control.

In the U.S., implementation of RHTP is generally taking much longer than initially anticipated which affects not just Acarix but all applicants. We understand that additional work around program details, including return-on-investment requirements and accountability measures, is contributing to the extended timeline. Acarix remains actively engaged and well positioned as the program advances, and we now hope for a result in Q4, although no guarantees can be made.

In KSA, the regulatory review of the CADScor® System also continues to progress. We believe the ongoing regional conflict may be contributing to longer regulatory timelines; however, we have not received any indication of a change in the underlying approval process.

Acarix remains confident in the progress of both initiatives and will provide further updates when material information becomes available.

About the CADScor® System

The CADScor System is a point-of-care diagnostic aid that uses highly sensitive acoustics and advanced computational analysis and AI to assess a patient's coronary blood flow. It calculates a patient-specific CAD-score and combines it with clinical risk factors to rapidly indicate the risk of significant coronary stenosis, prior to potential secondary evaluation. The system produces a result in under 10 minutes and is designed to rule out significant CAD with at least 96% negative predictive value at point of care. The CADScor System has been used in over 60,000 patient assessments, is built on 15+ years of R&D covered by 45 patents, is CE-marked in accordance with EU MDR 2017/745, and has received FDA De Novo clearance as a diagnostic aid for symptomatic patients with suspected CAD.

About Acarix

Acarix is a Swedish medical device company that develops solutions for rapid, AI-based rule-out of coronary artery disease at the point of care. The CE-marked and FDA De Novo-cleared CADScor System is intended for patients experiencing chest pain with suspected CAD and is designed to support clinical decisions by helping reduce unnecessary, invasive, and costly diagnostic procedures. Acarix is listed on the Nasdaq First North Premier Growth Market in Stockholm (ticker: ACARIX) and cross-traded on the OTCQB market in the US (ticker: ACIXF). The Company's Certified Adviser is Tapper Partners AB. For more information, please visit www.acarix.com

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Attachments

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