Q-linea receives US FDA 510(k) clearance for the ASTar® System

Q-linea AB (publ) (OMX:QLINEA) today announces that the U.S. Food and Drug Administration (FDA) has granted 510(k) market clearance for the company's ASTar® System, enabling market launch to hospitals and laboratories in the United States.

Stuart Gander, CEO of Q-linea, said: "The approval is a significant step for Q-linea in the infectious disease diagnostics field in the U.S. Feedback from hospitals that have had early access to ASTar has been very positive, and we are excited to now be able to bring the system to labs across the U.S., which will make a real difference for patients with severe blood stream infections. We are pleased with the panel of drug-bug combinations which has been approved."

According to the Centers for Disease Control and Prevention, at least 1.7 million adults in the United States develop sepsis each year and nearly 270,000 die as a result. ASTar enables rapid therapeutic response to sepsis directly from a positive blood culture in approximately six hours, giving physicians the tool needed to improve patient outcomes and reduce mortality.

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About Q-linea

Q-linea is an innovative infection diagnostics company that primarily develops instruments and disposables for rapid and reliable infection diagnostics. Our vision is to help save lives by ensuring antibiotics continue to be an effective treatment for future generations. Q-linea develops and delivers preferred solutions for healthcare providers, enabling them to accurately diagnose and treat infectious disease in the shortest possible time. The company's lead product ASTar® is a fully automated instrument for antibiotic susceptibility testing (AST), giving a susceptibility profile within six hours directly from a positive blood culture. For more information, please visit www.qlinea.com.

This information is information that Q-linea is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-04-26 15:40 CEST.

Attachments

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