

Q-linea submits US market application to FDA

Q-linea AB (publ) (OMX: QLINEA) today announces that the company has submitted a 510(k) application to the FDA to gain US market authorization.

“This is a major milestone for us and an important step towards the US market. The next step will be the review of our clinical study data by the FDA, and I hope that the breakthrough designation we received in April 2022 could enable a prioritized review. We are encouraged about the results in the study, and I am looking forward to our future launch of ASTar in the USA,” said Jonas Jarvius, CEO of Q-linea.

About ASTar Instrument and ASTar BC G-Kit

ASTar Instrument and ASTar BC G-Kit already deliver the broadest answer regarding the combination of the number of antibiotics and the number of double dilution steps of each antibiotic, in a single analysis for gram-negative bacteria. The test enables the analysis of gram-negative bacteria, including difficult-to-grow so-called fastidious bacteria, which satisfies the need for rapid and comprehensive results to support optimal treatment decisions.

ASTar Instrument and ASTar BC G-Kit are CE-marked but not FDA 510(k)-cleared and not available for sale in the United States.

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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 2022-06-09 05:25 CEST.

Attachments

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