Q-linea prepare to start additional testing for US 510(k) application

Q-linea AB (publ) (OMX: QLINEA) today announces that, following feedback from the FDA, the Company will initiate additional testing to verify performance improvements that were implemented after the completion of the clinical validation in the 510(k) application for US market approval. The 510(k) application was originally submitted in June 2022.

The FDA's recommendation to conduct additional testing is prompted by an algorithm update and is primarily aimed at verifying the performance improvements brought about by the algorithm update. The update was made after the training data was expanded after the clinical study in the 510(k) application was completed. The training data is the basis for the machine learning algorithms that the ASTar software uses to calculate results. Similar performance improvements are already implemented and approved in the ASTar instruments approved for the European market.

The testing will be carried out at two locations in the USA and in the company's own microbiology laboratory in Uppsala and is estimated to include 300-350 samples from positive blood cultures.

"We are very pleased to have a clear strategy for this additional testing. Our goal is to complete the testing in the spring and to submit the data before the summer. It is very common that the FDA requests additional testing on submitted
510(k) applications. We waited quite some time for this feedback and believe it is because the pandemic led to an increased workload and longer lead times at the FDA," said Jonas Jarvius, CEO of Q-linea.

About ASTar Instruments 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 2023-02-14 19:55 CET.

Attachments

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