

Q-linea is taking the next step in the clinical study for the US market

Q-linea AB (publ) (OMX: QLINEA), a diagnostics company focusing on developing and delivering solutions for diagnosing infectious diseases accurately and quickly, today announces that the company has started the reproducibility part of the clinical study with ASTar for US 510 (k) market approval.

The structure of the study follows the design of the European clinical study, and the FDA has also approved that a large part of the study is performed in Sweden, something that is unusual, but naturally positive for Q-linea. As a step towards submission to the FDA for clinical approval, the company today announces that the next step has now been started at two Swedish hospitals and at Q-linea. The aim is to evaluate the reproducibility of ASTar (the ability to report the same response each time a sample is analyzed) as part of the US study.

"It's fantastic to now have started the next part of the American clinical study. The strong results from the European study, where we were able to show a very high reproducibility of 99.6%, make us confident in being able to meet or exceed FDA's requirement of 95%. The final part of the study is the prospective part (analysis of patient samples) at American hospitals, and we intend to start that part in the near future", said Jonas Jarvius, CEO of Q-linea.

Based on the US study, Q-linea is working to be able to submit a 510(k) application for the US market next year.

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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.

Attachments

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