Q-linea initiates US 510(k) clinical study for ASTar

Q-linea AB (publ) (OMX: QLINEA), a diagnostics company focused on developing and delivering solutions to diagnose infectious diseases accurately and rapidly, today announced that the company has started the 510(k) US clinical study for ASTar.

The structure of the study will follow the design of the European clinical study starting at Q-linea with analytical and retrospective spike-in samples and then expand to US hospitals for the prospective part of the study. The size of the US study will be slightly larger compared to the European study with an expanded analytical study according to FDA guidelines and is planned to include up to 150 prospective patient samples each from participating hospitals. The focus of the study will be antimicrobial susceptibility results for gram-negative bacteria, including fastidious, directly from positive blood cultures.

"It feels fantastic to have started the US clinical study and with the recent strong results from the European study we anticipate an equally strong result from the US study. FDA allowed Q-linea to perform a majority of the US study at the Q-linea site and parts of the reproducibility study at Swedish hospitals and this is of course very positive. Our goals it to submit the 510(k) application to FDA during 2021" said Jonas Jarvius, CEO of Q-linea.

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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 2021-06-07 13:50 CEST.

Attachments

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