Q-linea receives positive response from the FDA for the design of the company's planned clinical study in the USA

Q-linea AB (publ) (OMX: QLINEA, announced today that the company has received the official response including a number of clarifications and very positive feedback from the US Food and Drug Administration, FDA, regarding the company's planned pivotal clinical trial with ASTar® in the United States.

“We are very pleased with the official feedback from the FDA which will have a very positive impact on the conduct of our clinical study in the US. We have received the clear guidance we wanted and we believe that the study can be carried out in a more straightforward way than previously estimated, as the FDA offers the possibility for Q-linea to perform parts of the study itself. This is good news that might also have benefits regarding the study's total cost and timeline", said Jonas Jarvius, CEO of Q-linea. “We also see that the feedback from the FDA could further improve the ASTar system's competitiveness”.

The FDA was positive to the study design proposed by Q-linea and also pointed to a new regulatory approach to include organism-antibiotic combinations for which there are currently no FDA-approved breakpoints. A prerequisite for getting these new combinations approved is that the applicant can demonstrate a clinical need and scientific support. Q-linea estimates that the company could become one of the first manufacturers to take advantage of this opportunity, which would further strengthen Q-linea's product offering in the USA.

Furthermore, the FDA was positive to reducing the number of samples in the clinical performance study for certain low prevalence organisms. This specifically applied to an organism that requires an enriched culture medium (fastidious supplement). “Of course, we are pleased that the FDA is opening up to this opportunity and this means that our ability to analyze fastidious and non-fastidious organisms in the same test in full can benefit patients”, said Jonas Jarvius.

The pivotal study with ASTar relates to the clinical and analytical performance of the system and will be conducted on at least three sites - two in the US and one in Europe, of which one is expected to be Q-linea's microbiology laboratory in Uppsala. The study is expected to start in the second half of 2020.

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About Q-linea
Q-linea is an innovative research, development and manufacturing company that primarily develops instruments and disposables for rapid and reliable infection diagnostics. Q-linea's 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 AB 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 08:00 CET on October 30, 2019.