

Q-LINEA PRESENTS POSITIVE INTERIM DATA FROM EUROPEAN TRIAL

Q-linea AB (publ) (OMX: QLINEA) today announced very good interim results from the pivotal European trial for the antibiotic susceptibility system ASTar®. EA was over 94 percent, CA over 97 percent and overall reproducibility over 99 percent. To achieve CE-IVD approval in Europe, EA and CA must exceed 90 percent.

Q-linea has analyzed the results from the majority of the samples in the clinical study and the interim results look very good. Q-linea will continue to analyze samples and collect samples from the clinic but does not foresee that the final analysis will deviate negatively from these results.

Essential Agreement (EA) i.e. giving the same result as the reference method on the concentration of antibiotics that kill or inhibit bacterial growth exceeded 94 percent. Categorical agreement (CA) i.e. giving the same classification of the bacterium within one of three groups (S.I.R) with respect to susceptibility to antibiotics exceeded 97 percent. To achieve CE-IVD approval in Europe, EA and CA must exceed 90 percent. In addition, reproducibility was very high and exceeded 99 percent.

"We are of course very happy that the interim results are so strong. We now have the data we need for the pivotal European study for ASTar. What remains is the completion of the technical file for CE-IVD registration and the completion of certain validation activities, but with these positive results, all launch activities can continue at an increased pace. The fact that we have included difficult and important antibiotics such as Colistin and fastidious bacteria shows that our technology is well prepared for the future," said Jonas Jarvius, CEO of Q-linea.

ASTar is a fully automatic and user-friendly system for antibiotic susceptibility testing (AST) with a short hands-on time and the capability to deliver a broad answer within approximately six hours for positive blood cultures.

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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 2021-03-31 14:21 CEST.

Attachments

[Q-linea presents positive interim data from European trial](#)