

Q-linea announces positive results from prospective study with ASTar

Q-linea AB (publ) (OMX: QLINEA), today announced positive results from a prospective patient study conducted together with Uppsala University Hospital. In the study, the ASTar system analyzed samples from 17 patients and the antibiotic panel consisted of 29 antibiotics. The results were very good and was well above regulatory requirements for EU and US.

The study was conducted in collaboration with the laboratory for clinical microbiology at Uppsala University Hospital. For three weeks, samples from 17 patients were collected and thereafter transported to Q-linea for analysis on ASTar. ASTar's antibiotic panel consisted of 29 antibiotic preparations to cover both fastidious and non-fastidious bacteria.

The Essential Agreement was 94.5 percent and the Categorical Agreement was 97.3 percent. Corresponding limit values for both CE-IVD approval and regulatory approval by the FDA are at least 90 percent in both categories.

“We are very pleased with these strong results. They bode well for the larger performance study that we expect to be able to start in the fall. That study will be even tougher and include more resistant bacteria, so we continue working on optimizing our algorithms,” said Jonas Jarvius, CEO of Q-linea. “The interest in testing ASTar has been great and we are glad that the study was conducted despite these challenging times for healthcare. This is a step to include additional hospitals in the upcoming clinical trial earlier than planned. The collaboration with Uppsala University Hospital has worked excellently and we look very positively at the opportunity of continued cooperation.”

The completed study is a preliminary study ahead of the prospective performance study with 80 to 100 patients, which Q-linea plans to start in the second half of 2020. That study result will be part of the documentation in the ongoing process for CE-IVD approval and submission to the FDA prior to the market launch of ASTar.

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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. 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.