Q-linea postpones start of the clinical trials

Q-linea AB (publ) (Nasdaq Stockholm: QLINEA), today announced that the clinical trials, in the United States and Europe, for the company's first product ASTar® are expected to begin in the second half of 2020. This is a postponement as the trials previously were expected to start in the first quarter of 2020. The reason is partly that Q-linea during the evaluation of ASTar during the autumn realized that the reliability of a third-party component needs to be improved. In addition, Q-linea have conducted several interviews with physicians in Europe and the US during the summer. With the new timeline, the company plan to investigate the possibility of including Meropenem-Vaborbactam (MER-VAB) into its antibiotic panel to provide a more comprehensive analytical result for patients with resistant bacterial infections.

“Of course, it feels disappointing to postpone our clinical trials and the launch of ASTar. However, we do not believe this affects the positive discussions we have with our possible future sales partners. Furthermore, we do not see that it affects the CE marking of the system. ASTar can still be launched at ECCMID in Paris as a research system, which means that we can place systems at customers for evaluation after ECCMID. This is a more traditional launch strategy with a longer test period of ASTar before commercial launch." said Jonas Jarvius, CEO of Q-linea.

The ASTar system has been thoroughly tested during the summer and autumn with strong overall results. However, an important component that Q-linea purchases from a third-party manufacturer has shown errors at a higher rate than acceptable. Q-linea work together with the supplier to jointly solve the problems, perform verification tests and then be able to place the systems at Q-linea’s clinical partners.

In connection with the development of the antibiotic panel, Q-linea has conducted a number of in-depth interviews with physicians in Europe and the US during the past months and in which the importance of MER-VAB has been emphasized, especially as increased antibiotic resistance has led to combination therapy becoming more common when treating patients with resistant infections. Within the timeframe of the new postponed timeline, the company will now explore the possibility to include MER-VAB in the antibiotic panel.

“If we can include MER-VAB in the antibiotic panel, this is another benefit. We are building ASTar and Q-linea with the aim of being a dominant player in the infection diagnostics market in the long term and a longer evaluation phase gives us better conditions to reach that goal,” said Jonas Jarvius.

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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 08:30 CET on October 22, 2019.