

## Q-linea can reach its main market faster than planned

**Q-linea AB (publ) (OMX: QLINEA), today announced that the company's first product ASTar™ is expected to launch on the company's main market, the U.S., three to four months than earlier communicated to take advantage of strong market interest and positive feedback from the US Food and Drug Administration, the FDA. The European launch is thus postponed to the same extent.**

In Q-linea's discussions with potential sales partners, increasing emphasis has been placed on the US market. Against this background, and because of the positive feedback Q-linea received from the US Food and Drug Administration, the FDA, indicating that data could be shared between the European and the US study, Q-linea has decided to change its launch strategy. As a result of our increasing focus on the U.S. market, efforts in Europe will be postponed three to four months.

“The new strategy means that we plan to conduct a joint study for the European and American markets. The European study will therefore be carried out somewhat later than previously communicated, while the American study, which we consider more urgent, is implemented earlier than planned. Overall, we expect to achieve a larger turnover faster, despite a quarterly postponement of the European study” says Jonas Jarvius, CEO of Q-linea.

Q-linea has previously received positive feedback from the FDA regarding the proposed clinical study for the US market. This means that data collected at one of the European hospitals can probably be used in the American study. A prerequisite is that the FDA approves the clinical study protocol, which Q-linea estimates could take place following an adaptation to the US requirements.

“It is very gratifying that the FDA considers that data can be shared between the American and the European studies. It should also mean that the scope and cost of the two studies will be slightly reduced than we previously expected,” said Jarvius.

Q-linea expects to submit data to the FDA in April 2020, three to four months earlier than communicated. Data will be partly based on the European study. The plan is now to launch ASTar in Europe in connection with the world's largest infection diagnostic conference ECCMID, held in Paris in April 2020.

**For more information, please contact:**

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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](http://www.qlinea.com).

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