

## Q-linea has completed its US market application

Q-linea AB (publ) (OMX: QLINEA) today announces that the company has completed its 510(k) application for US market approval. At the FDA's recommendation, Q-linea conducted additional analytical and clinical studies to support the company's 510(k) application for US market authorization.

Q-linea has had a continuous dialogue with the FDA, something that has likely been facilitated by AStar's Breakthrough Device designation. As previously communicated, however, it is difficult to assess the timing of market approval in the US. The FDA may have additional questions and the processing time is hard to estimate.

"The testing carried out during spring has gone according to plan and we have now compiled the results and completed our application in accordance with the feedback we received from the FDA. We have taken an important step closer to our goal and now hope for an effective review process", said Jonas Jarvius, president and CEO of Q-linea.

The FDA's recommendation to conduct additional testing was prompted by an algorithm update and was primarily aimed at verifying the performance improvements brought about by the algorithm update. The update was made as training data was expanded after the clinical study in the 510(k) application was completed. The training data is the basis for the machine learning algorithms that AStar's software uses to calculate results. Similar performance improvements for AStar are already implemented for the European market.

### For more information, please contact:

Jonas Jarvius, CEO, Q-linea AB

[Jonas.Jarvius@qlinea.com](mailto:Jonas.Jarvius@qlinea.com)

+46 (0) 70-323 77 60

Christer Samuelsson, CFO /IR, Q-linea AB

[Christer.Samuelsson@qlinea.com](mailto:Christer.Samuelsson@qlinea.com)

+46 (0) 70-600 15 20

### 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<sup>®</sup> 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).

**Attachments**

Q-linea has completed its US market application