

Press Release

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QluCore's software for cancer diagnostics on its way to obtaining CE certification

- Precision diagnostics crucial for targeted cancer treatment

QluCore, a company listed on Nasdaq First North, is in the process of obtaining CE certification for its cancer diagnostic software. The company has contracted the British Standards Institution (BSI) as the Notified Body to conduct the Conformity Assessment of QluCore Diagnostics' acute lymphoblastic leukemia devices. BSI will assess the Technical Documentation package against the IVDR. QluCore expects to obtain CE certification by February 2025.

The assessment is being conducted according to the new In Vitro Diagnostic Regulation (IVDR), which is a European Union regulation for in vitro diagnostic medical devices. The assessment period includes time for QluCore to make any necessary revisions. It is worth noting that IVDR is a new regulation, and this is QluCore's first application. The timeline indicates that QluCore Diagnostics will be certified and ready for launch in February 2025.

"QluCore Diagnostics is the future solution for diagnostics, enabling expanded possibilities for personalized cancer treatment. Our goal is to obtain a CE certification for the first model targeting pediatric leukemia," says Carl-Johan Ivarsson, CEO of QluCore.

"It is an important milestone for us to be able to contract BSI and establish a timeline for the ongoing work. This agreement is even more significant given that the availability of Notified Bodies has been, and remains severely limited," adds Carl-Johan Ivarsson, CEO of QluCore.

QluCore Diagnostics is a modular software, meaning that it provides disease-specific models based on machine learning that enable patient classification into subgroups. The model for acute lymphoblastic leukemia (B-cell precursor) is the first of several areas. Development work is also underway for solutions in lung cancer and bladder cancer.

"The program becomes an important part of the workflow for clinical diagnostics of leukemia. By offering our model for acute lymphoblastic leukemia, healthcare providers gain access to an approved solution for RNA-seq-based diagnostic support. This makes it easier to determine the type of treatment a patient should receive" says Carl-Johan Ivarsson.

Precision diagnostics for cancer have rapidly evolved in recent years, driven by next-

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generation sequencing (NGS). Until now, the focus has been on mutations and variants in the genetic code, which have been used for patient stratification and decision-making in cancer treatment. However, there is growing interest in techniques based on measuring gene activity levels as they provide additional opportunities to describe the appropriate treatment for a patient.

QluCore Diagnostics will be available to buy directly from QluCore's own sales force in Europe.

Certified Advisor

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About QluCore

QluCore is a leading provider of new generation intuitive bioinformatics software for research and precision and companion diagnostics. QluCore's mission is to make it easier to analyze the huge amounts of complex data generated by innovations in the fields of genomics and proteomics by providing powerful visualization-based bioinformatics data analysis tools for research and precision diagnostics. QluCore Omics Explorer software is a Do-It-Yourself bioinformatics software for research in the life science, plant- and biotech industries, as well as academia. QluCore Diagnostics and QluCore Insights are software platforms with built in AI-based machine learning for multi-omics companion and precision diagnostics. QluCore was founded in 2007 in Lund, Sweden and has customers in about 25 countries around the world, with sales offices in Europe and North America, and distribution in several countries in Asia. QluCore is listed on the Nasdaq First North Growth market. www.qlucore.com

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Image Attachments

[PR BSI Acute Lymphoblastic Leukemia](#)

Attachments

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