

Press Release

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Swedish innovation evaluated for clinical diagnosis of pediatric leukemia

– Qlucore Initiates Performance evaluation study as part of obtaining CE marking

Qlucore, a leader in software development for precision cancer diagnostics, has taken a significant and crucial step towards obtaining a CE marked solution, initiating a formal performance evaluation study in Sweden and Denmark. Results from the study are expected early in 2024.

The specific cancer to be tested in the study is acute lymphoblastic leukemia (BCP-ALL) in children. Leukemia in children, i.e. BCP-ALL continues to have high mortality rates and treatment-related complications.

IVDR regulations for medical devices require products to be CE marked prior to use in healthcare diagnostics. Once the ongoing performance evaluation study is completed, Qlucore will be required to compile a study report and create a technical file that will be submitted to a Notified Body. BSI (British Standards Institute) has been contracted as the Notified Body, and they will conduct the formal review regarding the product's safety and performance. The estimated timeframe for regulatory approval and CE marking of Qlucore Diagnostics BCP-ALL is February 2025.

The intended use of the software from Qlucore is to qualitatively analyze genetic alterations that may cause the disease condition BCP-ALL. This analysis is based on gene activity levels and the identification of gene fusions. Classification into genetic subgroups is performed using a machine learning-based classifier, which presents a probability of the patient belonging to one of six defined subgroups. *

"Entering this next phase of CE marking is a significant and important step for us," says Carl-Johan Ivarsson, CEO of Qlucore. "It indicates that our solution has reached a high level of maturity, and it is time to transition from internal testing to evaluation in a clinical setting. We look forward to the results that will determine the performance we can communicate."

Intended customers are clinical laboratories in Europe, and exact usage will be determined in conjunction with regulatory approval.

*) This is a simplified description of the intended use of the product. The exact form of use will be determined in connection with the regulatory approval.

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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 easy to use bioinformatics software for research in the life science, plant- and biotech industries, as well as in 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

Image Attachments

[PR BSI Acute Lymphoblastic Leukemia](#)

Attachments

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