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Press Release

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IndiTreat® Image Uploader gets IVD CE-Mark

2cureX, a company pioneering the use of 3D tumoroids for drug sensitivity prediction in patients with cancer, announced today the CE-Marking of the IndiTreat® Image Uploader, a software application that is critical to enable IndiTreat® testing at hospitals. The company announced on October 26th 2023 that it would focus all resources on making IndiTreat® testing available at hospitals worldwide by accelerating the development of an automated IVD system.

IndiTreat® Image Uploader: linking the images from each hospital to 2cureX AI algorithms

The decentralized testing model implies that hospitals will conduct the whole IndiTreat® process inhouse, using the automated IVD system (instruments, reagents, consumables, and software) provided by 2cureX. Nevertheless, the image analysis and report generation steps will be performed at 2cureX central servers, using the company's proprietary software and AI algorithms. In this way, customers will benefit from an ever-growing global database to compare a patient's results with others in similar circumstances.

It is, therefore, crucial that the tumoroid images captured at the hospital can be transferred to the central server in a smooth, fast, safe and secure way.

The IndiTreat® Image Uploader is a software application designed to facilitate the secure transfer of IndiTreat® screening image files from a local computer to a centralized server for downstream data processing and analysis. The software controls users' rights and ensures data integrity and authenticity, streamlining the upload process and enhancing the overall productivity of IndiTreat® operations at hospitals labs.

"We are very satisfied with this milestone", says Jacob Thastrup, Director of Product Development. "The development and launch of an automated IVD system – a project we named ZENITH – involves developing and CE-marking not only the instrument, but also its associated reagents, consumables and software. We are developing and CE-marking more than ten products in parallel, so each one we complete is a very important achievement".

The IndiTreat® Image Uploader has been CE-Marked in compliance with Regulation (EU) 2017/746, also known as IVD-R, and is the third 2cureX product under this regulation, after the IndiTreat® Specimen Collection Kit and IndiTreat® Shipping Container launched on August 30th 2023.

Decentralization of IndiTreat® testing to trigger mainstream use

IndiTreat® is currently offered as a service, out of a centralized lab location – a model used by all suppliers of Functional Drug Sensitivity Tests – but experience shows that this model is not suitable for mainstream use as it disrupts the hospital workflows and requires too complex sample logistics. By enabling in-house testing at customer's labs, 2cureX aims at leveraging its first mover advantage and building a global leader position in an emerging segment that is expected to become a multi- billion USD per year market.

"Our teams are doing an excellent job in reaching the milestones of the ZENITH project. We are determined to be the first company to launch an automated IVD System for hospital in-house Functional Drug Sensitivity Testing", says Fernando Andreu, CEO of 2cureX.

For more information about 2cureX:

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About 2cureX

2cureX is a leader in cancer drug sensitivity testing and has developed the IndiTreat® (Individual Treatment) family of tests. Starting from a sample of the patient's tumor, IndiTreat® creates thousands of 3D replicas (tumoroids) and predicts the tumor response to the different available drugs, providing the physician with valuable information to make the treatment decisions.

The first three IndiTreat® tests are aimed at optimizing treatment decisions in patients with metastatic colorectal cancer (IndiTreat® Start for first line of therapy, IndiTreat® Extend and Explore for third line). Additional tests are under development to cover other stages of colorectal cancer as well as other gastrointestinal cancers.

According to several reports, the total yearly expenditure in cancer-related In Vitro Diagnostic (IVD) tests exceeds 17.5Bn USD worldwide, from which 2.5 Bn USD are tests directly related to therapy decision making, with a CAGR of 12.7%. Despite this, only one third of all cancer treatments are supported by one of these tests. IndiTreat® aims at filling this gap and making Precision Oncology available to all cancer patients.

The company is listed on Nasdaq First North Growth Market in Stockholm (symbol: "2CUREX"). For more information about 2cureX visit www.2cureX.com

Certified Adviser: Redeye AB

Attachments

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