Fruebjergvej 3
DK – 2100 Copenhagen
Denmark
www.2cureX.com

Press Release

11 October 2023 12:45:00 CEST

2cureX advances towards IVD-R compliance by securing a contract with a Notified Body

2cureX, a company pioneering the use of 3D tumoroids for drug sensitivity prediction in patients with cancer, announced today the signature of a contract with a Notified Body under Regulation (EU) 2017 /746 on in vitro diagnostic medical devices. This important milestone has been reached according to the originally communicated plan and brings the company closer to its goal of having all its products CE-marked under the new IVD-R regulation before May 2025.

As part of the effort to get the company and its products compliant with the new IVD Regulation (IVD-R) before the end of the transition period (May 2025), 2cureX has announced today that it has signed an agreement with a Notified Body to assess and certify the conformity of its IndiTreat® products.

The Notified Body will in the coming months conduct the Conformity Assessment, which includes an audit of 2cureX Quality Management System and, given IndiTreat® classification (Class C), a thorough review of all the technical documentation related to the Safety and Performance Requirements. Based on these assessments, the IndiTreat® products will be certified and allowed to display the CE Mark in compliance with IVD-R.

Only 10 Notified Bodies are designated for IVD-R

The availability of Notified Bodies has been one of the major bottlenecks in the transition of IVDs and other Medical Devices from the previous European Directives to the new European Regulations. As of today, only 10 organizations have been designated by EU state members as Notified Bodies according to Regulation (EU) 2017/746 on in vitro diagnostic medical devices and getting their commitment to review the Technical Files and Quality Management Systems of the companies has proven to be a challenge. Medtech Europe (the European Medical Technology industry association) estimated in their report *Transition to the IVD Regulation*, published in February 2023, that more than half of the SMEs in the industry did not yet have an agreement with a designated Notified Body.

“We are very satisfied with this agreement”, says Manuel Martin, Director of Quality Assurance and Regulatory Affairs, and PRRC (Person Responsible for Regulatory Compliance) of 2cureX. And continues: “First, we had to find an available Notified Body, and then we had to prove that our Quality Management System is up to the requirements. It’s been a long process but now we are sure that we can keep the announced timelines for our IVD-R transition”.

New regulation

The new Regulation (EU) 2017/746 (IVD-R) rules the placing on the market and putting into service of in vitro diagnostic medical devices (IVD), replacing Directive 98/79/EC (IVD-D). The regulation entered into full force on May 26th, 2022, and its main changes relate to device classification, stricter oversight of manufacturers by Notified Bodies, introduction of the "Person Responsible for Regulatory Compliance" (PRRC), the requirement of UDI marking for devices, common specifications, Eudamed registration, and increased post-market surveillance activities.

For more information about 2cureX:

Fernando Andreu, Chief Executive Officer
E-mail: fa@2curex.com
Telephone: +45 2279 5399
www.2curex.com

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

2cureX advances towards IVD-R compliance by securing a contract with a Notified Body