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

Press Release

30 August 2023 08:30:00 CEST

2cureX launches its first two IndiTreat® products CE-marked under the new IVD Regulation

2cureX announced today the launch of two IVD products – IndiTreat® Specimen Collection Kit and IndiTreat® Shipping Container – that have become the first to be CE-marked under the new IVD-R by the company. The IndiTreat® Specimen Collection Kit is a replacement of the previous IndiTreat® Specimen Collection Set, while the IndiTreat® Shipping Container is a new device to ensure optimal conditions during transportation of patient samples from hospitals to the 2cureX testing facilities.

The IndiTreat® test is performed on patient-derived 3D tumoroids that are biological replicas of the patient's original tumor. To grow these 3D tumoroids, it is essential that the biopsy taken from the patient reaches the 2cureX testing facilities in optimal conditions.

The IndiTreat® Specimen Collection Kit contains a specialized ready-to-use, single-use buffer capable of supporting the viability of specimen samples during transportation, as well as a temperature logging device to monitor the temperature that the specimen has been exposed to during shipment. The IndiTreat® Shipping Container is a specialized single-use shipping container capable of supporting specimens with optimal shipping conditions by providing stable temperatures within 2-8°C in the sealed payload compartment for at least 48 hours.

The two new products will start to be commercialized immediately throughout the 20 countries where 2cureX has commercial operations, directly or through its network of distribution partnerships. Today's news are in line with our launching plans for 2023, and will not affect our revenue expectations for the year.

A critical step of the process

"We are very proud of this launch", says Jacob Thastrup, Director of Product Development at 2cureX. And continues "These two products combined ensure the required control and traceability during transport, which is a critical step of the process. Furthermore, this CE-marking shows the progress we have made in terms of our readiness for IVD-R, where the requirements for the development and documentation of the product are much more stringent than they were in the past".

First to market

"As far as we know, 2cureX has been the first among all players in the Functional Drug Sensitivity Testing field to CE-Mark under IVD-R the components for sample transportation", says Fernando Andreu, CEO of 2cureX. "This is a testimony to our leadership in this space, and to the effort of our team in turning the challenge of the European regulatory changes into an opportunity for differentiation".

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 profiling 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 drugs available, providing the physician with valuable information to make 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, +46 8 121 576 90, certifiedadviser@redeye.se

Attachments

2cureX launches its first two IndiTreat® products CE-marked under the new IVD Regulation