

Press Release

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2cureX discloses status of 2022 plans, goals for 2023 and its estimates of potential market development in the coming years

2cureX, a company pioneering the use of 3D tumoroids for drug sensitivity prediction in patients with cancer, will hold a Strategy Deep-Dive session on November 15th. In this event, the company will explain in detail the market in which they are operating and provide information about their estimates on size and evolution of that market. 2cureX will also update participants as to its strategy and the status of execution of their product development and commercial plans for 2022. Finally, the company will disclose their goals for 2023.

Shifting paradigms in mCRC treatment selection

2cureX aims to bring the benefits of Precision Oncology to all colorectal cancer patients. Precision Oncology is defined as “the right drug for the right patient at the right time”, or in other words, matching an individual patient to the best treatment option for him. Unfortunately, in the case of metastatic colorectal cancer, the six drugs and drug combinations that are used as “backbone” do not have any biomarker that can be used by the oncologist to select the right one for each individual patient. Patients are treated without any indication as to whether the chosen drugs will work or not.

Through a new approach called Functional Drug Sensitivity Testing (f-DST), 2cureX can measure the sensitivity of an individual tumor to each drug, so the oncologist can use this information to make an informed treatment decision.

A new segment in the *in Vitro Diagnostics* (IVD) space

Functional Drug Sensitivity Testing is a new segment in the IVD market. IVD is a market of approximately 86.5Bn USD per year, with an estimated CAGR of 3.3% over the next 10 years. This is a very concentrated industry, with only nine companies accounting for almost 75% of the market, while the remaining 25% is distributed among a long tail of more than 500 companies.

The f-DST segment is still emerging, as this technology is not being used today in routine clinical practice. Based on internal modeling, using parameters from the uptake dynamics of related technologies like Next Generation Sequencing and liquid biopsies, 2cureX has estimated that this segment can reach a global size of 100M USD in 2026, and 500M USD in 2032, for metastatic colorectal cancer alone.

Focus on colorectal cancer (CRC)

2cureX has a strategy of focusing on colorectal cancer, which is the third largest cancer type, with 1.9M new cases every year and projected to grow to 3.2M per year in 2040 mainly due to population aging and changes in lifestyle. Current approaches to personalized treatment in CRC are very limited, and this is recognized by oncologists as a burning clinical need.

The company aims to build a sustainable leading position in this segment through the advantages of being the first entrant, developing superior understanding of the dynamics of this segment, building a portfolio of products focused on specific customer needs and creating customer loyalty as a consequence of the above.

The IndiTreat® technology

Drug Sensitivity Testing dates back to the 1940s as a way to identify the most efficacious antibiotics against bacterial infections in individual patients. This concept was transferred to testing of anti-cancer drugs in the 1980s. While the predictive value of these early cancer tests was limited, the development of three-dimensional microtumors has dramatically improved the accuracy since these 3D structures replicate the genetic and functional properties of the patient's tumor.

2cureX has developed the IndiTreat® technology based on 3D microtumors and f-DST and launched three CE-marked tests (IndiTreat® Start, Extend and Explore) to support therapy decision-making in metastatic colorectal cancer.

While the tests are currently offered as a service (samples arriving from hospitals all over Europe are tested in the company's laboratory in Copenhagen), the goal is to develop a system of instruments and reagents that will allow in-house testing at the hospitals, thus enabling a larger market for the company. 2cureX has a collaboration with Hahn-Schickard Institute in Freiburg, Germany, for automating the critical steps of IndiTreat® and the latest prototype instrument was transferred to 2cureX in Copenhagen early November.

2cureX's announces the beginning of the development project for a new IndiTreat® product (IndiTreat® Neo) that will support treatment decisions in earlier stages of colorectal cancer, thus expanding the current market opportunity.

Commercial strategy – Execution status

Through their network of distributors in Europe, 2cureX is conducting a range of activities to increase the awareness of oncologists and pathologists about f-DST in general and IndiTreat® in particular. This includes being present at conferences (like ESMO GI this year), presentations at hospitals (thus the importance of an extensive sales network in each country), publications, webinars, social media, etc....

2cureX had announced a goal for 2022 of being present and active in 20 countries in Europe. As of November 15th, the company is covering 17 countries, through distributors or direct operations, and has confirmed the goal of 20 for the end of the year.

The activities are targeting first specific profiles of customers, labelled "Innovators" and "Early Adopters", who are estimated to be around 15% of total customers. For these groups to request the test, they need to have tried it themselves and confirmed it works according to the expectations. Thus, the company is offering them a trial program called IGNITE, or alternatively, participation in clinical studies.

While the announced goal for the year was to have 30 hospitals enrolled in the IGNITE program, as of 15th of November there are 15 hospitals enrolled. 2cureX and its distributors are in conversations with 39 additional hospitals but the 2022 goal has been revised to 20 hospitals enrolled. The key reason for the delay is the very long and slow internal processes in the hospitals, mainly review and approvals of legal documentation (contracts, GDPR compliance, patient consents...) and coordination of the different departments involved in the IGNITE program.

The company is nevertheless very encouraged by the response of the oncologists and remains optimistic about capturing a significant share of the market as it develops in the coming years. The competitive analysis covering 36 companies worldwide shows that 2cureX is still ahead in bringing this new technology to clinical routine practice.

Outlook 2023 – Following 2cureX’s progress

2cureX’s core strategy remains unchanged, in the sense that the company will continue to focus on the European region (but open to opportunities for collaboration with other companies, especially in US and Middle East) and in the area of colorectal cancer. All activities in 2023 will be directed towards pushing the adoption curve of f-DST forward and capturing a significant share of this emerging market by addressing the identified catalyzers throughout the curve.

In particular, in 2023 the main areas to watch will be:

- The expansion of the IndiTreat® user base and the number of patients tested, through the commercial activities of distributors, and continuing to offer Innovators and Early Adopters the chance to use IndiTreat® (via the IGNITE program or through participation in clinical studies).
- The geographic expansion within Europe to reach some important markets we are missing today.
- The advancement of the project to enable IndiTreat® testing at hospitals, as in Europe, the possibility of hospital in-house testing is an important driver for adoption of f-DST in clinical routine.
- The advancement in the development of our next IndiTreat® test (IndiTreat® Neo), aimed at early stages of colorectal cancer (addressing non-metastatic disease).
- The establishment of additional clinical studies to support clinical practice change and reimbursement activities for our current products.

The specific KPIs 2cureX will be using to monitor these activities are as follows:

Number of patient samples tested	> 500
Number of countries with IndiTreat® presence	> 25
IndiTreat® decentralization	Establishment of 1 pilot Hospital Lab
IndiTreat® Neo development	Finish Performance Assessment phase
Number of clinical studies started	2
Revenue	> 6 M SEK, of which 3M SEK from sales (the rest coming from grants or other sources)

It is important to mention that 2023 will not be an expansive year in terms of Operating Expenses, as corresponds to the multi-faceted crisis we are living in. Therefore, all these activities will be conducted in a lean and efficient manner, as 2cureX been doing in the past.

Learn more at the Strategy Deep-Dive Session on November 15th

To learn more about the market opportunity that 2cureX is addressing, the company strategy, the competitive situation and the plans of the company for 2023, join the session by clicking [here](#).

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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

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This information is information that 2cureX is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2022-11-14 08:30 CET.

Attachments

[2cureX discloses status of 2022 plans, goals for 2023 and its estimates of potential market development in the coming years](#)