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Oncocyte Switches Gears on Transplant Test Commercialization, Plans to Launch LDT Next Year

By Molika Ashford
December 23, 2021

NEW YORK – Oncocyte is accelerating commercialization plans for its first non-oncology assay, based on the Therasure transplant rejection monitoring technology it gained with its recent acquisition of Chronix Biomedical, executives said in a call with investors last week.

The company had previously planned to market the digital PCR test initially in Europe, and to launch it in the US as an IVD kit in order to differentiate itself from existing competitors CareDx and Natera.

But according to CEO Ron Andrews, the firm now intends to launch a lab-developed test in the US for three indications — kidney, liver, and heart transplants — by the end of the first half of 2022, applying for coverage under an existing Medicare local coverage determination.

Oncocyte still intends to adapt the Therasure test to a distributable kit eventually. Based on market research, the company has concluded that transplant centers want test results with same-day turnaround, so offering a digital PCR kit for in-house testing could help the company make its case against competitors.

In the meantime, though, Andrews said that given the reimbursement landscape, an LDT offering could become an important near-term revenue driver for Oncocyte while it moves through the long process of seeking coverage for its oncology tests.

Considering current reimbursement values for heart and kidney transplant tests already on the market, Andrews estimated an approximately $2 billion US market. "We're very excited about getting into this market. We know there are great companies that are [already] here, but we believe we have a unique opportunity," he said.

The company's primary differentiation strategy will be banking on the fact that the Therasure assay has been validated for liver transplants as well as heart and kidney transplants. Although competitors like CareDx have said they also intend to extend the use of their tests into liver and other organs, Andrews said Oncocyte hopes to be the first to market for liver transplant patients, focusing specifically on this population when it launches next year.

"[This is] a very prominent organ transplant in the United States, so we'll start with our focus there, but also add heart and kidney as the time and opportunity presents itself," he added.

Describing the company's immediate strategy, Andrews said the next few months will be dedicated to moving forward with commercialization of Therasure in Europe.

Oncocyte already has a partner in northern Europe: Hanover, Germany-based Amedes Genetics. The goal is to find a partner in southern Europe in the first half of next year and then file for reimbursement in a select group of countries, beginning with Germany.

Simultaneously, the firm is working on transferring the technology from the Chronix lab in Germany to its own lab in Nashville, for a launch in 2022. "Once we get that done, the goal is to establish partnerships with transplant centers and then ultimately move those centers into our clinical trial

phase," Andrews said, describing plans for a trial that would be complete by the first quarter of 2023 and hopefully support a submission to the US Food and Drug Administration for clearance of a kit version of the assay.

For its lab-developed test, Andrews said that Oncocyte is confident it can meet CMS's requirements for coverage for Medicare patients. Under an LCD issued in April for molecular transplant rejection assays, tests seeking coverage must demonstrate analytical validity and equivalence in sensitivity and specificity to other already-covered tests with the same intended use that measure the same or directly comparable analytes. These include tests marketed by CareDx and Natera.

"CMS has already given this blanket local coverage decision ... so our [first order of business] is to go and prove that we are equal to the technology that was approved for that LCD," Andrews said. Citing publications on the assay from studies performed by Chronix in years past, he added that Oncocyte believes that it can handily make the case to Palmetto.

"We feel pretty confident with the data we have that it meets the LCD requirement," added Padma Sundar, Oncocyte's chief commercial officer.

Asked during the call whether the push to enter a new disease space might stretch resources thin, requiring the company to fundraise, Andrews said that there has been significant interest from potential partners, which he declined to name.

"We think there are ways to get [this] business up and going that would mean minimal dilution to shareholders, given the partners that are at the table. I can't say a lot more than that, but our goal, obviously, is to make sure that we get Therasure to market and get that revenue," he said.