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Oncocyte launches immunotherapy response prediction test to bring cancer cells out into the open

By David Godkin, Staff Writer

TORONTO – Oncocyte Corp. launched Determaio, an immunotherapy response prediction test it said is "the first to comprehensively assess the tumor microenvironment." This is important because of how smart cancer cells are in that microenvironment, Oncocyte CEO Ronnie Andrews told *BioWorld*, commandeering natural tissue repair biology and condensing immunological T cells so they back off attacking cancerous tissue.

"Our test shows patient tumors that are either poised to respond to a specially designed drug called an immunological checkpoint inhibitor (ICI) or tumors that are in the process of hiding from the immune system," said Andrews. "Once you shut down the tissue repair mechanism the tumor is exposed again and the ICIs, combined with the immune system, get rid of the tumor."

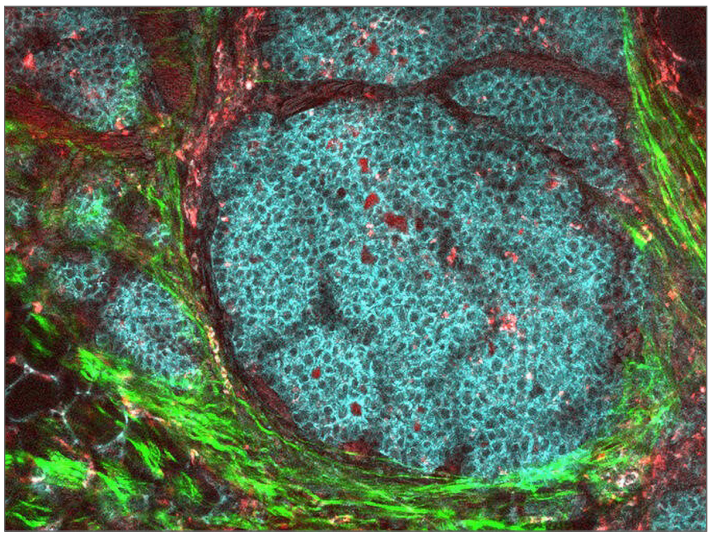
Search and destroy

Using a drug to trigger an immunological response to fight cancer is one thing. Obtaining a response durable enough to keep up the fight is something else altogether. In this instance, the immune system is impeded by cancer's rear-guard seizure of tissue repair cells. Once immobilized, these turn the battlefield over to the now undetectable cancer cells.

The key is to fully understand that battlefield, said Andrews, using Determaio, a 27-target multivariate gene expression test that measures in biopsy the ratio of immune modulating cells and tissue repair cells. "That ratio tells us where the patient is in terms of their readiness for a full immune response," said Andrews. "Are they ready for just an immune therapy or does it need something else to bind to and inhibit that tissue repair mechanism?"

That something else depends on a further distinction between large scale genetic testing that identifies "hot" tumors likely to respond to treatment and "cold" tumors. Cold tumors are typically ignored in genetics testing because they don't respond to key immunological biomarkers such as the all-important PD-L1 biomarker.

"By not looking at the cold part of the tumor environment they are missing a subset of the patient population," said Andrews. "We put the cold and hot together and are able to characterize the tumor microenvironment with more precision and identify more patients who will need therapy."



Oncocyte Corp.'s Determaio is a 27-target multivariate gene expression test to assess the tumor microenvironment.

Andrews again stressed the importance of a durable immunological response, "so these patients can be put on a combination therapy of ICI and a tissue repair inhibition drug and have the best chance to live." It's an ICI's ability to bind with PDL receptors so the immune system can detect and destroy cancer cells "that has made it a class of drug that has really put the market on fire in the past five years," said Andrews.

Not only are pharmacology companies producing ICIs at a rapid pace, med-tech firms are building platforms designed to prognosticate therapeutic outcomes. But no company other than Oncocyte has developed a diagnostic platform for assessing the tumor microenvironment and predicting the likely response to

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immunological therapy, according to Andrews.

Equally important, he added, has been Oncocyte's recent work with emerging drug companies that can make these inhibitor drugs available to work in conjunction with Determaio's precision diagnostics. "So when a patient's score indicates a warm tumor, we can start them on both the checkpoint inhibitor and a repair inhibition drug and get the best response to the therapy," said Andrews.

This doesn't mean others are not working in these same tumor microenvironments, including Memorial Sloan Kettering Cancer Center and Huntsville, Ala.'s Hudson Alpha Institute for Biotechnology. But, "We've taken our test out of the research and translational medicine environment that you see at Memorial Sloane and Hudson Alpha," he said.

"We are reducing to practice the knowledge about what's going on in the tumor microenvironment and bringing to market the first test that can rapidly identify this phenomenon of hot and cold environments and deliver it at low-cost."

Failure not an option

Oncocyte has studied "well over 1,000 patients around the world," demonstrating Determaio's ability, Andrews said, to predict response to ICIs across multiple tumor types, including lung, breast, bladder and renal cancers. Oncocyte's first randomized prospective study looking at the Atezo ICI developed by Roche Holding AG's Genentech Inc. was presented at a recent ESMO congress "and was really important," said Andrews. "Prospective trials with drug really allow us to go to market. We were able to call up patients who specifically responded to the ICI Atezo for a durable response, as opposed to results confounded by patients who got both Atezo and chemo."

Determaio is being assessed in the U.S. at 10 clinical sites which order the test as part of a 60-day early access program in which "chain-of-custody" quality monitoring of biopsy samples will be conducted. This is to ensure patients benefit from the appropriate therapies by the end of the test.

"Did we get the right sample, did we get enough tumor in the sample, and when we ran the test, did we report it for the right patient to the EMR?" These are vital boxes that must be checked off as well, said Andrews.

Tests will be conducted through December and early January at which point the data will be reviewed. If the test performs as expected "our regulatory and quality control teams will say you're good to go and we'll go to the rest of the market," said Andrews.

His expectations for the test remain firm: It has the potential to help inform the optimal use of immunotherapy treatment for more than 1 million eligible patients annually in the U.S. alone. But the data must be reproducible for the right patient each time it is used, said Andrews. "Failure is not an option. We don't have that luxury in medicine."

Oncocyte currently derives its revenues from the sale of its lung cancer test Determarx and pharma services. Third quarter results released Nov. 9, 2021, showed a net loss of $13.8 million, or $0.15 per share, as compared to $6.8 million, or $0.10 per share, for the third quarter ended Sept. 30, 2020.

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