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Where Tomorrow LIVES

Determining immunotherapeutic responsiveness one test at a time

Precision diagnostics and monitoring company Oncocyte is developing the most comprehensive and rapid tumor-microenvironment gene-expression test to assess immunotherapeutic responsiveness. Combined with the company's other tests, it provides a complete solution for cancer immunotherapy management and monitoring.

Oncocyte, a California-based precision diagnostics and monitoring company, aims to improve patient outcomes by providing personalized insights that inform critical decisions throughout the patient care journey. The company's pipeline includes a number of proprietary tests to identify early-stage markers relating to the aggressiveness of cancer, assess the mutational status of a tumor, assess whether treatment is working, monitor long-term recurrence, and more. It provides a comprehensive suite of molecular testing services to support both the academic and commercial development of cancer drugs.

More recently, Oncocyte has focused on creating diagnostics to support the development and clinical application of cancer immunotherapies. Immunotherapies have fundamentally changed the oncology space over the past decade by dramatically increasing the ability to provide highly targeted interventions and long-lasting outcomes for a range of cancer indications, but the overall response rate to such treatments still hovers around 15%. Accurately predicting likely responders and monitoring their response during treatment have become key components in maximizing the potential of these therapies for patients.

Oncocyte is now rapidly advancing a clinically validated gene-expression test designed to assess immunotherapeutic responsiveness across multiple components of the tumor immune microenvironment (TIME) in order to predict individual responses to immunotherapies. The test, called DetermaIO, is currently an RT-PCR test but can also be run on a next-generation sequencing platform, and the company is developing an in vitro diagnostic kit version with a global platform partner (Fig. 1).

"Over the past decade, eligibility for and accessibility to checkpoint-inhibitor drugs and other immunotherapeutics has expanded to over 50% of all cancer patients, but still only one in six patients will benefit therapeutically," said Rob Seitz, head of immune oncology of Oncocyte. "DetermaIO will help identify those patients who will most likely benefit from a particular immunotherapy and, importantly, those who would not benefit from it, in order to maximize the outcomes for the former and to minimize the loss of precious treatment time and adverse effects for the latter. Ultimately, our goal is to help realize the promise of precision care for each patient with cancer worldwide."

In addition to DetermaIO, Oncocyte is developing DetermaCNI, a blood test to detect cancer progression by looking at changes in levels of circulating tumor DNA in plasma with greater than 90% sensitivity and 95% specificity. The combined use of DetermaIO and DetermaCNI—in addition to several other tests in development by the company, which address the entire continuum of cancer and transplant care—is expected to provide a complete solution for clinicians to predict and monitor responses to immunotherapeutic interventions. Oncocyte is seeking additional development and commercialization partners to accelerate the clinical implementation of both tests.

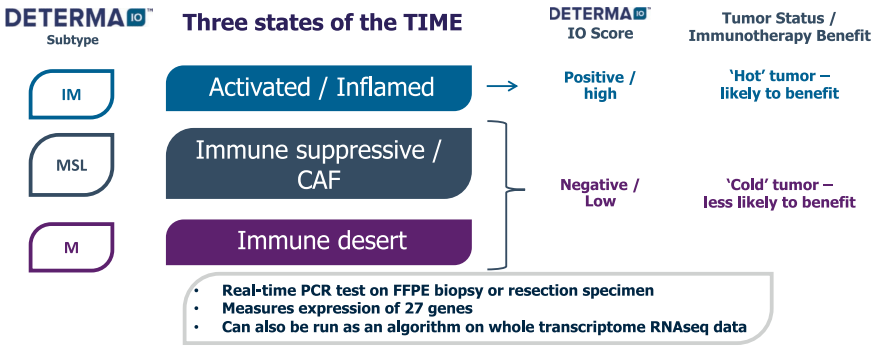

Fig. 1 | Investigating the tumor microenvironment. Oncocyte is developing the most comprehensive and rapid gene-expression test on the market. It is designed to assess the immunotherapeutic responsiveness of the tumor microenvironment and predict individuals' responses to immunotherapies. CAF, cancer-associated fibroblast; FFPE, formalin-fixed paraffin-embedded; IM, immunomodulatory; M, mesenchymal; MSL, mesenchymal stem-like.

Boosting immunotherapeutic responsiveness

Improving the response rate to immunotherapeutic interventions is contingent on improving the ability to modulate the naturally evolving immunosuppressive nature of the TIME. Many treatment strategies under consideration involve the development of immunomodulating drugs to be used either with, or after, checkpoint inhibitors to respond to the tumor's own changes in the TIME. Therefore, innovative testing strategies are likely to be needed to identify the patients best suited for a variety of immunotherapeutic interventions, and to accelerate the development of improved immunotherapeutic strategies.

Oncocyte's DetermaIO consists of a 27-target, multivariate gene-expression test performed on formalin-fixed paraffin-embedded biopsy specimens. It measures the presence of subtypes of infiltrating inflammatory cells (sensitivity to immune checkpoint), and the presence or absence of a differentiated stromal microenvironment. Powered by a proprietary algorithm that integrates the mRNA (gene expression) data, DetermaIO interprets the results to determine the physiology of both the tumor and the surrounding TIME, and helps predict responsiveness to immuno-oncology therapies.

In 11 clinical studies across six tumor types, DetermaIO has consistently proven to be accurate at identifying patients who will respond to immunotherapy, including those who might have been missed by testing for programmed death ligand 1 (PD-L1), tumor mutational burden or other biomarkers, as well as patients who are unlikely to respond but had been initially misidentified as candidates for immunotherapy using standard tests.

"At Oncocyte, our mission is to make sure patients everywhere will have access to fast and accurate tests to select the most appropriate therapies in consultation with their doctors," said Doug Ross, CSO of Oncocyte. "A growing body of clinical evidence is establishing the importance of accurately characterizing the status of the TIME for informing the use of immune therapies. Our recent data suggests that DetermaIO provides the most accurate analysis of all the relevant pathways, and provides novel information that can improve patient care."

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