Oncocyte Announces Oral Presentation of New Data on Its DetermaIO™ Immunotherapy Response Test at the European Society for Medical Oncology Annual Meeting

Sep 20, 2021

Randomized clinical trial data from NeoTRIPaPDL1 study establishes DetermaIO as a predictive biomarker of immunotherapy response

Trial Investigators found DetermaIO outperformed 80 other immune related signatures in TNBC

IRVINE, Calif., Sept. 20, 2021 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics and monitoring company with the mission to improve patient outcomes by providing clear insights that inform critical decisions in the diagnosis, treatment, and monitoring of cancer, today presented new data in an oral presentation at the European Society for Medical Oncology Congress (ESMO) 2021 evaluating DetermaIO™ as a biomarker for immune therapy response. The results demonstrated in a randomized clinical trial setting that DetermaIO, a 27-gene precision diagnostic, is predictive of response to neoadjuvant immune checkpoint inhibitor treatment of triple negative breast cancer (TNBC), and support the potential of DetermaIO to serve as a precision diagnostic for this important class of novel therapies with expanding indications across tumor types.

Commenting on the trial results, Ron Andrews, Chief Executive Officer of Oncocyte, stated, "Demonstrating the utility of DetermaIO in the rigorous setting of a randomized, therapeutic clinical trial is a landmark accomplishment for Oncocyte, and simply put, we are very enthusiastic about the results. These data from a prestigious international clinical trial provide important confirmation of DetermaIO's capacity to work as a precision diagnostic across the checkpoint inhibitor class of therapies which we believe can benefit both drug development and add precision to patient treatment decisions. We are thrilled to add this new data to the compelling collection of studies that validate the assay's utility in Lung, TNBC, and Bladder cancers, and across four approved immunotherapies - Keytruda®, Opdivo®, Tecentriq® and Imfinzi® - suggesting a potential pan-cancer and pan-immunotherapy utility in both primary and metastatic settings. We look forward to advancing DetermaIO toward clinical launch in Q4, allowing us access to a US market estimated at three billion dollars."

Key results and conclusions from the late breaking oral presentation titled, "*Predictive value of gene-expression profiles (GEPs) in the Neo TRIPaPDL1 trial*", include:

- The utility of DetermaIO (IO Score) was evaluated as part of the NeoTRIPaPDL1 (NCT02620280) study, an international clinical trial that enrolled 241 Stage I-III TNBC patients from seven countries across Europe and Asia, and randomized them into two study arms: neoadjuvant treatment with chemotherapy or with chemotherapy in combination with an immunotherapy

- A key goal for DetermaIO was to assess its utility as a predictive diagnostic for immune therapy, a successful result for a precision diagnostic shows that patients benefit *only* in the combination of a positive test and receiving the specific immunotherapy (IO score and atezolizumab in this study)
- In the group of IO score positive patients who received both immunotherapy and chemotherapy, response rates were substantially higher compared to those who received chemotherapy alone (71% versus 51%)
- Conversely, in the IO score negative population, no significant difference in response rates was seen (40% versus 44%)
- The IO score positive patients who received atezolizumab demonstrated a predictive response at least 20% higher than the other three groups and was statistically significant as measured by an interaction test ($p = 0.029$)
- 42.7% of the patients were IO score positive demonstrating that the test is identifying a substantial subset of TNBC patients who may benefit from immune checkpoint therapy
- Taken together, these data demonstrate the potential of DetermaIO to be a precision diagnostic to identify both responders and non-responders to immunotherapy. This shows its potential to inform the selection of patients who will benefit from treatment while also helping to avoid treatment associated toxicities for those who will not benefit.

Giampaolo Bianchini, M.D., Head of the Breast Cancer Group at the San Raffaele Scientific Institute, and trial investigator said, "Looking at pathologic complete response in this prospectively, randomized Phase III trial, IO score demonstrated the ability to identify those TNBC patients who benefitted the most from the addition of atezolizumab, and this was supported statistically by a significant test of interaction. Notably, we assessed more than 80 immune-related signatures and none of them showed similar significant tests of interaction. In addition, IO score was significantly more associated with pCR in atezolizumab arm than any other immune-related signatures. This observation underscores the capability of the test to measure features across the tumor microenvironment, including those intrinsic to the tumor (mesenchymal features) and extrinsic to the tumor such as immune infiltration."

Rob Seitz, Head of Immune Oncology at Oncocyte, said, "One of the most common questions we get from experts in the immune oncology field is how does DetermaIO compare to other immune related signatures. The additional research of Dr. Bianchini's group showed that the IO score clearly distinguished itself from the numerous immune related signatures that were tested, a result that demonstrates DetermaIO has a unique and pivotal role versus other tests in selecting patients for immunotherapy. This is an extremely important milestone, where for the first time, by evaluating the tumor micro environment or TME, we have a precision diagnostic for immunotherapy that can find the right treatment for the right patient with specificity for response."

On Tuesday, September 28th, 2021 from 1-2PM EST, the Company will be hosting a Key Opinion Leader event with Dr. Bianchini and Priyanka Sharma, M.D., Professor of Medicine at the University of Kansas Medical Center to discuss the unmet need for identifying patients with triple-negative breast cancer (TNBC) who will respond to immunotherapy, with Dr. Bianchini highlighting the NeoTRIPaPDL1 randomized clinical trial ESMO data.

Abstract and Presentation Details:

- Title: **Predictive value of gene-expression profiles (GEPs) in the Neo TRIPaPDL1 trial**
  Abstract #: LBA12
  Session type: Late-breaking abstract and oral presentation
  Presenter: Bianchini, G.

Authors: Bianchini, G., et al.
Date and time: September 20, 2021, 17:30 CET

About The NeoTRIPaPDL1 Study

The NeoTRIPaPDL1 (NCT02620280) study is an international clinical trial comprising patients from seven countries across Europe and Asia which randomized TNBC patients into two treatment arms: treatment with chemotherapy or treatment with chemotherapy in combination with an immunotherapy. 241 patients with Stage I-III triple negative breast cancer were randomized to either receive immunotherapy plus chemotherapy, or standard of care chemotherapy, prior to their surgery (the neoadjuvant setting). The trial investigators have previously reported initial response data describing how the patient responded with the strongest response being no evidence of the tumor at the time of surgery (pathologic complete response or pCR).

About Oncocyte
Oncocyte is a precision diagnostics and monitoring company with the mission to improve patient outcomes by providing clear insights that inform critical decisions in the diagnosis, treatment, and monitoring of cancer. The Company, through its proprietary tests and pharmaceutical services business, aims to help save lives by accelerating the diagnosis of cancer and advancing cancer care. The Company's tests are designed to help provide clarity and confidence to physicians and their patients at every stage. DetermaRx™ identifies early-stage lung cancer patients who are at high risk for cancer recurrence and who may benefit from adjuvant chemotherapy. DetermaIO™, a gene expression test currently used as a research-use only tool, assesses the tumor microenvironment to predict response to immunotherapies. The Company's pipeline of tests in development also includes DetermaTx™, which will assess the mutational status of a tumor; blood-based monitoring test DetermaCNI™, and long-term recurrence monitoring test DetermaMx™. In addition, Oncocyte's pharmaceutical services provide companies that are developing new cancer treatments a full suite of molecular testing services to support the drug development process.

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consistent and precise analytic results on a commercial scale, potential interruptions to supply chains, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, and the need to obtain third party reimbursement for patients' use of any diagnostic tests Oncocyte or its subsidiaries commercialize, and risks inherent in strategic transactions such as the potential failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, potential greater than estimated allocations of resources to develop and commercialize technologies, or potential failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly such statements should be evaluated together with the many uncertainties that affect the business of Oncocyte, particularly those mentioned in the "Risk Factors" and other cautionary statements found in Oncocyte's Securities and Exchange Commission filings, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Oncocyte undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Investor Contact
Bob Yedid
LifeSci Advisors, LLC
646-597-6989
bob@lifesciadvisors.com

Media Contact
Megan Kernan
Westwicke/ICR Healthcare PR
Tel: 203.856.4326
Terri.Clevenger@icrinc.com

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