Oncocyte Presents New Data at 2021 American Association for Cancer Research Annual Meeting Demonstrating Potential for Pan-Cancer Utility of DetermaIO™

Apr 10, 2021

Achieved primary endpoint demonstrating significant correlation between DetermaIO and two-year overall survival rate to atezolizumab in metastatic bladder cancer

DetermaIO identified additional immunotherapy responsive patients missed by commonly used biomarkers

Data supports potential utility of DetermaIO test across multiple solid tumors as predictor of response to Immune Checkpoint Inhibitor therapy in estimated $3 billion market in the United States

KOL Webinar discussing results to be held on April 19 at 11:30 AM EDT/8:30 AM PDT

IRVINE, Calif., April 10, 2021 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, presented new data at the American Association for Cancer Research (AACR) Annual Meeting 2021, being held virtually from April 10-15, 2021. The presentations featured studies of Oncocyte's novel predictor of immunotherapy response, DetermaIO™, demonstrating test performance in bladder cancer, now the third cancer type, suggesting potential applicability across multiple cancer types. DetermaIO has previously been shown to predict immunotherapy response in lung and breast cancers in studies using four different approved checkpoint inhibitors – Keytruda® (pembrolizumab), Opdivo® (nivolumab), Tecentriq® (atezolizumab) and Imfinzi® (durvalumab).

At the conference, Oncocyte debuted data in bladder cancer in two studies, including one highlighted in a podium presentation. The poster, titled "
Pathway modeling to translate the 27-gene immuno-oncology algorithm into bladder cancer," detailed the application of the DetermaIO test and proprietary algorithm for the classification of metastatic bladder cancer. This study demonstrated a novel approach of looking at the tumor microenvironment (TME) at a genomic scale, as well as validating the use of the test, without any further modification, in bladder cancer to assess its association with Immune Checkpoint Inhibitor (ICI) response. A link to poster can be found here and accompanying explanation can be found here.

During the podium presentation, titled "
Validation of a 27-gene immuno-oncology algorithm in metastatic urothelial carcinoma treated with an im mune checkpoint inhibitor
," Robert Seitz, Head of Immune Oncology at Oncocyte and lead author of the study, revealed the results of a prospectively defined analysis of clinical trial results from the IMvigor210 study of atezolizumab

(TECENTRIQ®), an immunotherapy used to treat bladder and other cancers. A replay of the presentation can be accessed *here*.

"The study achieved its primary endpoint demonstrating a significant correlation between DetermaIO and two-year overall survival to atezolizumab, and with Genentech publishing similar analyses with other biomarkers, we were able to compare DetermaIO to those biomarkers currently in clinical practice as well as those being explored for potential future use," said Mr. Seitz. "We were able to demonstrate that DetermaIO identifies additional responsive patients that were missed by more commonly used biomarkers including – PD-L1 and TMB. We applied the same predefined threshold for test positivity in bladder cancer as we did for lung and breast cancer, providing increased confidence in DetermaIO's utility across multiple solid tumor types."

"We are pleased to present these results as we work towards the identification of a test that can clearly identify patients who are most likely to respond to immune therapies. The growing body of evidence for the use of DetermaIO as a predictive test for response to a class of immune therapies will help focus clinical studies, potentially help resuscitate failed therapy indications, and provide more informed management for use of these powerful therapeutics," noted Doug Ross, M.D., Ph.D., Chief Science Officer of Oncocyte. "We look forward to sharing data in additional tumor types as the year progresses and also to working with BioPharma and Pharma companies to improve outcomes for their trials."

Oncocyte's DetermaIO test measures the expression of 27 genes and combines them with a proprietary algorithm to classify the entire tumor immune microenvironment present in solid tumor biopsy samples. The Company's previously released data demonstrated that the combination of measuring the "hot" inflammatory immune response combined with the "cold" immune repressive signature coming from the wound response in tumor specimens, is strongly associated with response to ICIs in lung and breast cancer. With an estimated 750,000 patients potentially eligible for immuno-oncology (IO) therapy in the U.S. annually, and nearly 5,000 clinical trials currently evaluating these drugs, the Company believes it is well-positioned to participate in the estimated $3 billion pan-cancer immune therapy diagnostic market*.

"These results are timely and provocative in the setting of recent voluntary withdrawals of atezolizumab and durvalumab in patients with platinum-refractory advanced bladder cancer due to insufficient efficacy noted in randomized Phase III studies. Regardless, even in these studies, there remain patients who benefit from ICIs and have durable responses to treatment. Thus, a biomarker strategy to identify these patients remains a significant unmet medical need and has the potential to explain a lack of efficacy seen in unselected patient populations. As new treatments for metastatic urothelial cancer have emerged, a better predictive biomarker for ICIs has become even more important as a means to identify those patients likely to benefit from immunotherapy and spare those unlikely to benefit so that they may be treated with other active agents," noted Mamta Parikh, M.D., M.S., Medical Oncologist and Assistant Professor at UC Davis Comprehensive Cancer Center (UCDCC) with a specialty in urinary tract cancers. "In this bladder cancer study, a single arm study of atezolizumab in metastatic urothelial cancer, DetermaIO was able to identify a group of platinum-refractory patients – 41% of treated patients – who had a significantly superior overall survival upon treatment with atezolizumab of 12.9 months, compared to 8.0 months in the "all comer" population treated with the therapeutic."

KOL Webinar:
Oncocyte will host an educational webinar about the results of this study on April 19 at 11:30 AM EDT/8:30 AM PDT that will feature presentations by David Gandara, M.D., Professor-Emeritus and Director of the Thoracic Oncology Program at the UC Davis Comprehensive Cancer Center (UCDCC), a specialist in urogenital oncology and Chair of the Oncocyte Scientific Advisory Board, and Mamta Parikh, M.D., M.S., Assistant Professor at UCDCC, a medical oncologist who specializes in the treatment of genitourinary malignancies including kidney, bladder, prostate, ureteral cancers. Dr. Gandara will review

the status and challenges of current ICI biomarker strategies and Dr. Parikh will put these novel findings of DetermaIO relevance to bladder cancer in the context of late-stage bladder cancer. Register in advance for the webinar *here*.

Details and links to Oncocyte's oral and poster presentations are highlighted below:

Mini Symposium Oral Presentation:
Title:
Validation of a 27-gene immuno-oncology algorithm in metastatic urothelial carcinoma treated with an immune checkpoint inhibitor
Authors: Robert S. Seitz (presenter), Douglas T. Ross, Tyler J. Nielsen, David R. Hout, Brock L. Schweitzer, Oncocyte Corporation
Abstract Number: 23
Session Title: MS.CL01.01-Biomarkers
Session Date and Time: Saturday, April 10, 2021, 1:50 PM EDT – 2:00 PM EDT

Summary:
The study achieved its primary endpoint that demonstrated a significant correlation between DetermaIO and two-year overall survival in atezolizumab treated metastatic bladder cancer. DetermaIO identified additional responsive patients missed by other biomarkers. These data demonstrate DetermaIO's ability to identify patients more likely to respond to ICI therapy in a third and new tissue indication, in addition to Triple Negative Breast Cancer (TNBC) and non-small cell lung cancer (NSCLC), along with a fourth different ICI agent.
The algorithm and classification threshold were established prior to testing in all three studies, as presented in the poster presentation (see below), and was not changed between the different tissue indications. Taken together, these data support the potential use of the 27-gene DetermaIO test as a pan-cancer predictor of response to ICI therapy.

Poster Presentation:
Title: Pathway modeling to translate the 27-gene immuno-oncology algorithm into bladder cancer
Authors: Robert S. Seitz (presenter), Tyler J. Nielsen, Brock L. Schweitzer, David R. Hout, Douglas T. Ross, Oncocyte Corporation
Abstract Number: 175
Session Title: PO.BSB01.02 - Application of Bioinformatics to Cancer Biology
Session Date and Time: Saturday, April 10, 2021, 8:30 AM EDT - 11:59 PM EDT

The link to the poster presentation is available *here*.

Note: The following registered trademarks are the property of their respective owners: TECENTRIQ® - Genentech, Inc.; KEYTRUDA® - Merck Sharp & Dohme Co.; OPDIVO® - Bristol Myers Squibb Company; IMFINZI® - AstraZeneca group of companies.

*Grand View Research estimates.

About Oncocyte Corporation
Oncocyte is a molecular diagnostics company whose mission is to provide actionable answers at critical decision points across the cancer care continuum. The Company, through its proprietary tests and pharmaceutical services business, aims to help save lives and improve outcomes by accelerating and optimizing the diagnosis and treatment of cancer. The Company's tests and services present multiple opportunities to advance cancer care while also driving revenue growth for the Company. Oncocyte launched DetermaRx™, a test that identifies early-stage lung cancer patients who are at high risk for cancer recurrence post-resection and predicts benefit from adjuvant chemotherapy. Oncocyte has also

launched DetermaIO™, a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies, as a research use only tool for pharmaceutical and academic clinical trials. To complement DetermaIO™, the Company anticipates launching DetermaTx™, a test to assess mutational status of a tumor to help identify the appropriate targeted therapy, in the second half of 2021. The Company previously announced its planned acquisition of Chronix Biomedical Inc. and its TheraSure™ CNI Monitor test, and also plans to continue with the development of DetermaMx™ as the Company seeks to expand into the blood-based monitoring market. Oncocyte's pharmaceutical services provide pharmaceutical companies who are developing new cancer treatments a full suite of molecular testing services to support the drug development process.

DetermaRx, DetermaIO, DetermaMx, and DetermaTx are trademarks of Oncocyte Corporation. Therasure is a trademark of Chronix Biomedical Inc.

Oncocyte Forward Looking Statements. Oncocyte cautions you that this press release contains forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates," "may," and similar expressions) are forward-looking statements. These statements include those pertaining to the data presented at the 2021 American Association for Cancer Research (AACR) Annual Meeting, the potential use of DetermaIO across multiple tumor types, and other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, the potential impact of COVID-19 on our or any distributor's financial and operational results, risks inherent in the development and/or commercialization of potential diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of our third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to our or any distributor's supply chain, 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 we commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, greater than estimated allocations of resources to develop and commercialize technologies, or 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
Terri Clevenger
Westwicke/ICR

203-856-4326
Terri.clevenger@westwicke.com

Source: Oncocyte Corporation