Oncocyte Announces the Commercial Availability of DetermaRx™, the First Test for Chemotherapy Benefit Prediction in Patients with Early Stage Non-Small Cell Lung Cancer

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Leonard Cancer Institute at Mission Hospital, California and Florida Precision Oncology sign up as early access sites for the test

Canadian regulatory approval received allowing for path to reimbursement

IRVINE, Calif., Jan. 13, 2020 (GLOBE NEWSWIRE) -- Oncocyte Corporation (NYSE American: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the lung cancer care continuum, today announced that DetermaRx, formerly known as the Razor treatment stratification test, is now commercially available in the United States. Additionally, Oncocyte has received regulatory approval in Canada to begin distribution of DetermaRx in that country. DetermaRx enables the identification of early-stage lung cancer patients who may benefit from adjuvant chemotherapy post surgical resection. In a clinical study, high-risk patients identified by this test post-surgery and treated with adjuvant chemotherapy had a significant increase in survival rates.

Florida Precision Oncology and the Leonard Cancer Institute at Mission Hospital in Mission Viejo, California have signed up for early access to the test. The Leonard Cancer Institute at Mission Hospital is a brand new, state of the art regional cancer center and a part of the Providence St. Joseph Health network which consists of 119,000-plus caregivers and employees, serving 51 hospitals and more than 800 clinics delivering a comprehensive range of health and social services across Alaska, California, Montana, New Mexico, Oregon, Texas and Washington. Florida Precision Oncology, with locations in Aventura, Miramar and Boca Raton, is focused on delivering multidisciplinary cancer care in the community setting where most cancer is treated.

“We are thrilled to officially transform Oncocyte into a commercial-stage company as we make DetermaRx available to lung cancer patients in the U.S., and in the near future, Canada, who are in need of additional clarity when making treatment decisions after surgery,” said Ron Andrews, Chief Executive Officer of Oncocyte. “Under the current standard of care, approximately 30%-50% of stage I – IIA patients who have undergone surgery to remove lung tumors recur and die within five years of surgery. This is unacceptable. We believe DetermaRx, which has been extensively validated and published in top tier peer-reviewed publications, will address this critically underserved treatment decision point, helping physicians and patients make the right treatment decisions at the right time. We are also very pleased that Medicare, which covers ~70% of eligible patients, has proposed positive coverage for this test. This will promote broad access for patients who may stand to benefit from DetermaRx.”

Dr. Samer Kanaan, medical director for the lung program at Mission Hospital's Leonard Cancer Institute added, "Mission Hospital is honored to have been invited to serve as one of Oncocyte's early access partners. This new diagnostic tool will allow us to further enhance our comprehensive lung cancer treatment program and optimize post-surgical treatment decisions. This test serves an important unmet medical need, and I look forward to making it available to patients across the Mission Hospital and Providence St. Joseph networks."

Dr. Edgardo S. Santos, Founding Partner of Florida Precision Oncology, further commented, "There is no question that DetermaRx addresses an unmet need in thoracic oncology that we have had for decades. Lung cancer has an incidence of approximately of 225,000 patients per year; if we focus on those adenocarcinoma patients who have stage I and IIA disease, we are talking about 40,000 patients per year with a poor or suboptimal 5-year survival rate. If I have a tool such as DetermaRx which can identify those patients with early pathological stage ("supposedly cured") carrying a high-risk for recurrence (based on their genomic profile), there is no question in mind that it will significantly impact the survival of my patients. We also must keep in mind that with the advent of lung cancer screening, we will be able to identify more patients at early stages. Hence, we must be ready to have a discussion regarding therapy post-operatively. Besides poor features from the tumor that we have used for years to decide for or against postoperative chemotherapy, now DetermaRx brings molecular analysis on board which from my standpoint is a kind of personalized management. For example, not all stages IA are the same; some carry higher risk for recurrence than others. We must target them."

In bringing DetermaRx to market, Oncocyte will initially prioritize those cancer centers and physicians who manage the highest number of early stage lung cancer patients. Starting the first quarter of 2020, the Company will deploy an experienced salesforce which has a proven track record driving market leadership of novel high-volume molecular diagnostics.

About DetermaRx™

DetermaRx is a molecular diagnostic test that enables the identification of early-stage lung cancer patients who may benefit from chemotherapy following surgery, allowing them to be treated when their cancer may be more responsive to adjuvant chemotherapy. The test utilizes a gene expression analysis of 14 specific genes from a patient's tumor and a proprietary algorithm to stratify early stage NSCLC patients into one of two groups, one that may benefit from chemotherapy because of high risk of recurrence, and another that may avoid chemotherapy because of low risk of recurrence. DetermaRx is extensively validated and published with independent, blinded global studies in over 1,500 patients and seven publications in prestigious journals including the *Lancet* and *JAMA*.

About Oncocyte Corporation

Oncocyte is a molecular diagnostics company whose mission is to provide actionable answers at critical decision points across the lung cancer care continuum, with the goal of improving patient outcomes by accelerating and optimizing diagnosis and treatment. The Company is currently preparing to launch DetermaRx™, a treatment stratification test that enables the identification of early-stage lung cancer patients at high risk for recurrence post-resection, allowing them to be treated when their cancer may be more responsive to adjuvant chemotherapy. DetermaDx™, the company's liquid biopsy test in development, utilizes a proprietary immune system interrogation approach to clarify if a patients' lung nodules are benign, which may enable them to avoid potentially risky invasive diagnostic procedures.

Oncocyte 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” and similar expressions) are forward-looking statements. These statements include those pertaining to the time to complete and the results of the Company’s ongoing Clinical Validation study for DetermaDx, implementation and results of research, development, clinical trials and studies, commercialization plans, future financial and/or operating results, and future opportunities for Oncocyte, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, 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, the need and ability to obtain future capital, maintenance of intellectual property rights, and the need to obtain third party reimbursement for patients’ use of any diagnostic tests we commercialize. 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.

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