Oncocyte Launches First Real-World Evidence (RWE) Registry to Evaluate Biomarker Impact on Early-Stage Lung Cancer Treatment Decisions and Outcomes

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***P**redictive **A**ssay for **D**ecision **M**aking in **A**djuvant **T**herapy (PADMA) Registry to enroll more than 1,000 patients at 25 major hospitals treating lung cancer in the United States beginning Q4 2021*

Registry is intended to demonstrate the impact of biomarker adoption and precision medicine in creating personalized treatment options for early-stage lung cancer patients

IRVINE, Calif., Aug. 17, 2021 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics company with the mission to provide clear insights that inform critical decisions in cancer treatment, announced today the launch of a nationwide, prospective, real-world (RW) registry for patients with potentially curable early-stage lung cancer. The study is entitled the Predictive Assay for Decision Making in Adjuvant Therapy (PADMA) Registry.

This registry was created to collect data that may demonstrate the impact of biomarker-guided treatment decisions on patients with completely resected stage I and IIA non-squamous non-small cell lung cancer across multiple academic and community cancer centers in the United States.

Biomarker tests are playing an increasingly important role in guiding cancer treatment. Previously in early-stage breast cancer, molecular assays have shown significant utility in successfully identifying patients who are at higher risk of recurrence and who may benefit most from additional treatment over standard care to increase their chance of cure. In lung cancer, Oncocyte's DetermaRx™ identifies early-stage lung cancer patients who have a high risk of recurrence post-surgery, and who may benefit from standard of care adjuvant treatment, versus those would are likely cured from surgery alone and unlikely to benefit from additional therapy.

The PADMA Registry, which utilizes Oncocyte's DetermaRx™ test, will be the first RW initiative to evaluate the use of biomarkers in early-stage lung cancer. Nationwide enrollment will allow for all eligible patients to participate in the study, even if they do not live near a major cancer center.

"A registry like PADMA is important to the early-stage lung cancer community because we know that the earlier a patient is diagnosed and prescribed the right treatment strategy, the better that patient's long-term prognosis is likely to be," said Corey Langer, MD, the principal investigator of PADMA and Director, Thoracic Oncology at Abramson Cancer and Professor of Medicine at the Hospital of the University of Pennsylvania. "Molecular tests like DetermaRx™ assess a patient's risk of recurrence based on the

biology of their individual tumor and thereby may provide more confidence for physicians in determining whether the use of additional therapy is potentially warranted in the adjuvant setting."

Standard of care for patients diagnosed with Stage I or IIA lung cancer is surgical resection with the consideration of adjuvant chemotherapy in patients who have high-risk features based on clinical and pathological assessment (NCCN, 2021). The PADMA trial will perform molecular risk stratification using DetermaRx™ on eligible stage I-IIA patients along with EGFR mutational analysis (if indicated) to guide the choice of either adjuvant chemotherapy, targeted therapy, or a combination of both versus observation alone. Since this is a real-world, non-randomized observational study, treatment assignment will be made by the individual clinicians. During the study patients will be followed for recurrence regardless of their treatment decision.

The Company's DetermaRx™ test is a proprietary predictive test for early-stage lung cancer. In published studies, the assay has been shown to perform better than clinicopathological criteria alone in assessing risk of recurrence, which can lead to more informed treatment decisions at the time of surgery (Woodward, 2018). The Company believes that data from the PADMA Registry will demonstrate the impact of DetermaRx on physician decision making and outcomes in a real-world setting.

"We are thrilled to launch the PADMA Registry to provide physicians with critical information on the biology of their patient's tumor immediately after surgery," said Kim McGregor, MD, VP of Medical Affairs at Oncocyte. "At Oncocyte, we are laser-focused not only on the science behind our platform of tests, but also on how to get those tests to every patient – the democratization of health information starts with ensuring access to those who may not have the luxury of living close to a major research facility. Location should not determine the standard of care or insights they receive, and we look forward to working with the lung cancer community to bring clarity and an informed plan of action to every cancer diagnosis."

The launch of the PADMA Registry underscores Oncocyte's commitment to driving the highest science in order to empower surgeons, physicians, and their patients.

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 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.

Investor Contact

Bob Yedid
LifeSci Advisors, LLC

646-597-6989
bob@lifesciadvisors.com

Media Contact
Terri Clevenger
Westwicke/ICR Healthcare PR
203.856.4326
Terri.Clevenger@icrinc.com

Source: Oncocyte Corporation