Oncocyte Announces Peer-Reviewed Publication in Cancers Showing Utility of DetermaCNI™ Blood-Only Monitoring Test to Detect Recurrence Following Surgery in Epithelial Ovarian Cancer

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Data show DetermaCNI detects recurrence with higher sensitivity than standard of care biomarkers, high sensitivity with very low false positives

DetermaCNI is the first clinical-grade test to monitor for disease progression by detecting instability across the patient's entire genome in circulating tumor DNA, addressing an unmet need for millions of patients diagnosed with solid and hematological cancers

IRVINE, Calif., Jan. 04, 2022 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics 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 announced the publication of data showcasing the clinical utility of its DetermaCNI™ blood-based monitoring test in the peer-reviewed journal *Cancers*.

Oncocyte's DetermaCNI is a test used to measure and monitor cancer treatment success by detecting changes in circulating tumor DNA (ctDNA) levels, a minimally-invasive biomarker, during the course of treatment. The test is differentiated from other currently used methods because it does not require an upfront tissue sample, which can be hard to obtain, and also provides a genome-wide assessment as opposed to evaluating a subset of genes. The test converts cell-free DNA (cfDNA) next-generation sequencing (NGS) results into a proprietary genome-wide copy number instability (CNI) score which can be used to guide ongoing treatment decisions.

Results in this peer-reviewed publication demonstrated that DetermaCNI has the potential to address a significant unmet need for patients with primary epithelial ovarian cancer, which is the leading cause of death in gynecological cancers in Western countries. One of the goals of the study was to evaluate the role of the CNI score in monitoring patients' response to treatment, commonly platinum-based adjuvant chemotherapy following surgery. Specifically, blood samples were prospectively collected from 109 patients with high-grade ovarian cancer. cfDNA was extracted and analyzed from the blood plasma to determine the genome-wide CNI score after whole-genome NGS. DetermaCNI detected ovarian cancer at diagnosis with 91% sensitivity and in patients at recurrence on treatment with 86% sensitivity, with a very low false positive rate of 5% (95% specificity). These study results suggest the test has the potential to impact treatment change at crucial points for patients with ovarian cancer.

"DetermaCNI is a very important part of our strategy to provide a blood-based monitoring test to help physicians understand how a therapy is working and detect progression early in the treatment cycle to ensure the best outcome," said Ron Andrews, President and CEO of Oncocyte. "Today's announcement is

indicative of how powerful DetermaCNI can be in detection of disease, and given the data published to date on multiple tumor types, we believe it will complement our treatment decision test menu and ultimately become a treatment monitoring tool. These data build upon a previous data set published in *Clinical Cancer Research (Weiss et al.)*, which demonstrated the test's high accuracy in predicting progression on immunotherapy treatment, suggesting a broad application of this ctDNA based test for monitoring for progression and recurrence across cancers and treatment modalities. There is currently a blanket reimbursement approach by CMS for these types of monitoring tests at high value rates, and these types of publications help build the evidence we need to secure Medicare approval for this very lucrative market."

Ekkehard Schütz, MD, PhD, FAACC, CTO and Head of Liquid Biopsy and Monitoring at Oncocyte, said, "Monitoring tests which are less invasive and require no use of scarce tissue, have become an essential tool for the effective management of patients with cancer. ctDNA tests like DetermaCNI are valuable for monitoring because it has been shown that an increase in ctDNA is indicative of progression or recurrence, while a decrease can indicate effectiveness of treatment or surgery. In tracking this, DetermaCNI can give the reassurance that treatment is working, or if not, can provide the information needed to adjust treatment as necessary. For the two million patients diagnosed with cancer annually in the U.S., this brings invaluable peace of mind and a clear plan for the path ahead."

The paper can be found online at *Cancer's*website. This is the seventh publication that supports DetermaCNI, including a previous publication in immunotherapy monitoring

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.

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