Oncocyte Announces Definitive Agreement to Acquire Insight Genetics

Jan 10, 2020

Acquisition includes a potentially transformative immuno-oncology diagnostic test for the selection of therapy for cancer patients

Data presented at SITC 2019 demonstrated performance surpassing current predictive companion diagnostic tests

Includes a pharma trial lab compliant with 21 C.F.R. Parts 820 and 11

IRVINE, Calif., Jan. 10, 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 it has entered into an agreement to acquire, through a subsidiary, all of the outstanding capital stock of privately-held Insight Genetics, Inc. (IG), which has a history of impactful discoveries in the areas of lung and breast cancer.

OncoCyte entered into the agreement to access IG's technology and pharma service offerings. IG has a rich menu of relevant targeted therapeutic panels including two emerging therapeutic targets, RET and NTRK. IG's lead test is the "Immune Modulation" (IM Score), a gene expression test that measures the state of the immune system in biopsies from cancer patients to identify patients more likely to respond to PD-1/PD-L1 immunotherapies. Data presented at the 2019 Society for Immunotherapy of Cancer (SITC) Annual Meeting showed a strong association of the IM score with response to PD-1/PD-L1 targeted immunotherapy in lung cancer. Importantly, the IM Score test was superior to two currently marketed predictive companion diagnostic tests for immunotherapy selection, PD-1/PD-L1 IHC staining and tumor mutational burden (TMB). IG's lab has capacity to support clinical trials or assay design across a cadre of currently available commercial platforms to develop companion diagnostics and has successfully completed audits by major pharmaceutical and diagnostic companies. IG has performed assay development and clinical testing for leading pharmaceutical and biotechnology companies.

IG has achieved ISO 9001 certification, and it has a CLIA certified and College of American Pathology accredited lab that performs and develops proprietary cancer tests. IG's initial work identified and patented an ALK PCR translocation assay licensed by Qiagen. Its second initiative focused on Triple Negative Breast Cancer (TNBC), where IG developed a unique classifier that identifies six subtypes of TNBC, many of which have been demonstrated to have potential companion diagnostic applications to help women manage this deadly form of cancer.

"The addition of the Insight Genetics IM Score Test expands the decision points that OncoCyte's proprietary portfolio of tests addresses along the lung cancer continuum of care. To our knowledge this test is uniquely differentiated in that it characterizes immune response in cancer tissue in the context of characteristics of surrounding tissue. Combined with DetermaRx™ (previously the Razor treatment

stratification test), we now have proprietary tests that help manage key decision points in both early and more advanced lung cancer, " said Dr. Doug Ross, Consulting Chief Medical Officer of OncoCyte.

The principal investigator of IG's study, Dr. Gregory Vidal M.D, Ph.D., Lead of the Breast Cancer Research program at the West Cancer Center and Research Institute and Assistant Professor of Hematology/Oncology at the University of Tennessee Health Science Center added, "Identifying which patients will benefit most from immunotherapy remains an outstanding question for oncologists. The data presented by the Insight Genetics team at SITC is incredibly promising, and the oncology community is looking forward to seeing the impact the IM score test can have on a broader patient population. I believe it has the potential to improve patient outcomes and streamline the development of new therapies."

Padma Sundar, SVP Marketing and Market Access added, "According to a recent JAMA publication, close to 750,000 patients are eligible for immunotherapy treatment, representing a $2.2 billion total addressable market. The eligible patient population is anticipated to increase as immunotherapies are approved for the early stage adjuvant setting. In addition, there are close to 3,000 PD-1/PD-L1 ongoing clinical trials that are expected to recruit over 500,000 patients representing a large pharma services opportunity."

Al Parker, Chief Operating Officer of OncoCyte further commented, "We believe the combination of assets contemplated in this transaction will create enhanced value for our stakeholders and shareholders and advances our mission to provide actionable answers at critical and underserved decision points in lung cancer."

About the Proposed Merger and Principal Transaction Terms

Upon closing, OncoCyte will deliver closing consideration of approximately $12 million, consisting of $7 million in cash and $5 million of OncoCyte common shares, less deductions for transaction expenses and other liabilities.

The merger agreement provides for OncoCyte to pay a 10-year revenue share of not more than 10% of net collected revenues for current IG pharma service offerings and a tiered revenue share percentage of net collected revenues through the end of the lifecycle if certain new cancer tests are developed using IG technology. OncoCyte may pay contingent consideration of up to $6 million, in any combination of cash or OncoCyte common shares if certain milestones are achieved.

The closing of the merger with IG is subject to a number of conditions, including approval of the merger by IG's stockholders. OncoCyte will issue the shares in a private placement and has agreed to register the shares for resale. Additional information regarding the terms of the transaction will be provided in OncoCyte's Current Report on Form 8-K expected to be filed with the Securities and Exchange Commission on January 10, 2020.

Conference Call Information:

OncoCyte management will host a conference call and webcast today, January 10, 2020, at 4:30 p.m. ET. To access the call and webcast, please use the information below:

Dial in (US): 877-407-9716

Dial-in (International): 201-493-6779

Webcast: http://public.viavid.com/index.php?id=137640

About Insight Genetics

Insight Genetics is dedicated to improving the lives of cancer patients through advanced molecular diagnostics that enable precision cancer care. The company specializes in the discovery, development and commercialization of molecular diagnostics that detect specific cancer biomarkers in triple negative breast cancer and lung cancer to assist in guiding the effective diagnosis, treatment and monitoring of cancer. Insight Genetics partners with leading academic researchers, pharmaceutical and biotechnology companies, clinical reference laboratories, and IVD kit manufacturers to create new standards of care for cancer patients worldwide.

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 a treatment stratification test that enables the identification of early-stage lung cancer patients at high risk for recurrence, 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

OncoCyte cautions you that this press release contains forward-looking statements concerning, but not limited to, the acquisition of IG and the effects of the merger. The proposed merger described in this press release has not yet closed. All statements that are not historical facts (including, but not limited to statements that contain words such as "will," "likely," "may," "believes," "plans," "anticipates," "expects," "estimates," "intends," "seeks," "designs," "develops," "would," "future," "can," "could," "project," "potential," and similar expressions) are forward-looking statements. Factors that could cause or contribute to changes in the forward-looking statements include, but are not limited to (i) failure to realize the anticipated benefits of the acquisition, (ii) unexpected expenditures or assumed liabilities that may be incurred as a result of the acquisition, (iii) unanticipated difficulties in conforming business practices, including accounting policies, procedures, internal controls, and financial records of IG with OncoCyte, (iv) inability to accurately forecast the performance of IG resulting in unforeseen adverse effects on OncoCyte's operating results, (v) failure to satisfy the conditions to the completion of the acquisition on the anticipated schedule, or at all, (vi) synergies between IG and OncoCyte being estimates which may be materially different from actual results, (vii) failure to retain or integrate IG personnel, (viii) greater than estimated allocations of company resources to develop and commercialize IG technologies, or (ix) failure to maintain any laboratory accreditation or certification. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and commercialization of potential diagnostic tests or products, uncertainty in the results of clinical trials, changes to regulatory requirements, the need and ability to obtain future capital, protection of trade secrets and maintenance of other 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 ("SEC") filings, which are available on 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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