OncoCyte Announces Successful Completion of CLIA Validation Study of DetermaDx™

Jan 07, 2020

Company expects to complete clinical validation study of DetermaDx, previously DetermaVu™, in Q2 2020

IRVINE, Calif., Jan. 07, 2020 (GLOBE NEWSWIRE) -- OncoCyte Corporation (NYSE American: OCX), a developer of novel tests for the early diagnosis and management of lung cancer, today announced the successful completion of the CLIA Validation study of DetermaDx (previously DetermaVu), its liquid biopsy test in development to aid in ruling-out malignancy in lung nodules and potentially avoiding unnecessary invasive lung biopsies. With the completion of CLIA Validation, the Company will commence Clinical Validation, which, if successful, will establish the independent clinical performance of the test prior to commercial launch. Once Clinical Validation is completed and performance parameters are established, OncoCyte will begin preparations for commercial availability, including publication of the Clinical Validation results needed for CMS reimbursement dossier submission as well as the execution of additional clinical utility studies.

“We are encouraged by the completion of the CLIA Validation study, which demonstrates the successful transfer of the research assay to the rigorous environment of our commercial CLIA laboratory, including demonstration of excellent reproducibility,” said Lyndal Hesterberg, Ph.D., Chief Scientific Officer of OncoCyte. “Every year more than 1.6 million lung nodules are detected on imaging, but a majority of these nodules are found to be benign following an invasive diagnostic procedure such as a tissue biopsy, which can be associated with serious complications. DetermaDx has the potential to reduce the number of unnecessary procedures by identifying patients with likely benign nodules who could be routed to surveillance instead of an invasive diagnostic procedure.”

Dr. Hesterberg continued, “With lung cancer being the leading cause of cancer death, primarily due to late diagnosis, we believe DetermaDx has the potential to significantly change the paradigm for early stage lung cancer patients. This is a significant step towards making DetermaDx available to physicians and patients looking for actionable information that may be helpful for managing either incidental lung nodules or those detected by screening. We’re looking forward to continuing to advance DetermaDx, along with DetermaRx (previously the Razor treatment stratification test) for chemotherapy benefit prediction in early stage patients, to enable the diagnosis and treatment of lung cancer at its earliest stages when it is more treatable, thereby improving patient survival rates for this deadliest cancer.”

DetermaDx is a multigene assay that measures gene expression in circulating blood cells and, in conjunction with certain clinical factors, may help rule out cancer in patients with lung nodules identified by CT scans. The completion of the CLIA Validation study confirms the reproducibility, accuracy and precision of the gene measurements and the combined multivariate assay. OncoCyte tested

approximately 120 samples previously used in its R&D development study and successfully reproduced the results in the Company's CLIA laboratory.

About DetermaDx™

DetermaDx is OncoCyte's liquid biopsy test currently in development which has the potential to identify lung nodules that are likely benign, enabling patients to avoid potentially risky invasive biopsy procedures. The test utilizes a proprietary immune system interrogation approach and algorithm to integrate the results from RNA sequencing and clinical factors to deliver actionable findings to physicians, identifying a nodule as "likely benign" or "suspicious". OncoCyte estimates that a $1.8 billion annual market could develop in the U.S. for DetermaDx, depending on market penetration and reimbursable pricing.

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.

DetermaDx and DetermaRx are trademarks of OncoCyte Corporation.

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 DetermaDx Clinical Validation study, 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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Source: OncoCyte Corporation

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