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Veracyte Announces New Clinical Data Showing First-Ever Noninvasive Nasal Swab Test Can Enable Early Lung Cancer Detection and Diagnosis

Data presented today at CHEST 2019 Annual Meeting; Company plans to begin making test available in early 2021

Conference call and webcast today at 5:00 p.m. ET to review third quarter 2019 Financial results and the new nasal swab test data

SOUTH SAN FRANCISCO--(BUSINESS WIRE)--Oct. 22, 2019-- Veracyte, Inc. (Nasdaq: VCYT) today announced preliminary clinical data showing that the company's noninvasive nasal swab test – the first of its kind – can enable early lung cancer detection and diagnosis so that more lives can be saved. The new findings specifically show that the novel genomic test can accurately classify lung cancer risk in patients with lung nodules so that these patients can obtain the prompt diagnosis and potential treatment they need or may be monitored noninvasively. The findings will be presented today at the annual meeting of the American College of Chest Physicians® (CHEST) in New Orleans.

"Early lung cancer detection is key to saving lives. However, today when a potentially malignant lung nodule is found, physicians lack accurate and reliable tools to determine which patients require more invasive diagnostic evaluation and those who can be managed with noninvasive surveillance," said Carla R. Lamb, M.D., interventional pulmonologist at Lahey Hospital & Medical Center, in Burlington, Mass., who was a primary investigator on the nasal classifier study and will present the findings. "Given the nasal classifier's ability to more accurately classify cancer risk in patients with lung nodules, the test can help address this diagnostic gap, potentially helping to save more lives while also enabling patients to avoid unnecessary invasive procedures and reducing costs."

To develop and evaluate the test, Veracyte utilized nasal samples from over 700 patients with lung nodules found on computed tomography (CT) scans who were prospectively recruited and whose cancer status was subsequently determined. The researchers evaluated the test's performance on an independent blinded subset of 261 patients. The researchers determined the genomic test's ability to identify patients as high risk and low risk for cancer and then modeled its impact on patient care when the cancer prevalence is 25 percent. This aligns with the anticipated cancer prevalence among the people on whom the test will eventually be used.

Among patients whose nodules were benign, the genomic test classified over 40 percent as low risk for cancer, with a sensitivity of over 95 percent, meaning that these patients could be monitored noninvasively with a very low chance of missing a cancer. Among patients whose nodules were malignant, the test classified over 40 percent as high risk for cancer, with a specificity of over 94 percent, meaning these patients could be directed to more invasive diagnostic procedures and treatment, with a low rate of false positive results. The test's performance was consistent regardless of lung nodule size or location, as well as cancer subtype or stage.

Currently, physicians use clinical factors to calculate the risk of cancer when a lung nodule is found. However, these calculators vary widely in how they measure risk, produce differing results and have in some cases been shown to be less accurate than physician judgment alone. Researchers in the current study determined that the nasal swab test would identify over 70 percent more patients as "low risk" and 18 percent more patients as "high risk," as compared to one of the most widely used clinical risk calculators.

"Lung cancer is the leading cancer killer worldwide," said Bonnie H. Anderson, Veracyte's chairman and chief executive officer. "We are very encouraged by these preliminary data, which suggest that our nasal swab test has the potential to transform how this disease is diagnosed, enabling lung cancer patients to get the treatment they need sooner, while helping patients with benign nodules avoid unnecessary and costly invasive procedures. These data also mark the latest milestone in our long-term strategic collaboration with the Lung Cancer Initiative at Johnson & Johnson.* We look forward to finalizing and making our test available to physicians and their patients by early 2021."

Veracyte is collaborating with the Lung Cancer Initiative at Johnson & Johnson to advance the development and commercialization of novel diagnostic tests to detect lung cancer at its earliest stages, when the disease is most treatable. The collaboration, announced in January 2019, was formed to accelerate two key lung cancer programs for Veracyte: the commercialization of its Percepta® Genomic Sequencing Classifier on the company's RNA whole-transcriptome sequencing platform, which was achieved in June 2019, and the development of the first noninvasive nasal swab test for early lung cancer detection. Under terms of the agreement, Veracyte and the Lung Cancer Initiative at Johnson & Johnson have combined clinical study cohorts involving more than 5,000 patients with multiple years of clinical outcome data. Veracyte has contributed bronchial and nasal samples from its clinical trials, which are part of the company's extensive lung cancer-focused biorepository.

Veracyte's nasal swab test utilizes novel and proven "field of injury" science, which identifies genomic damage associated with lung cancer in current or former smokers using a simple brushing of the person's nasal passage. The company is developing the test on its RNA whole-transcriptome sequencing and machine learning platform, which leverages highly granular genomic information to answer specific clinical questions.

Veracyte estimates that the market opportunity for its nasal swab test, when used to assess lung cancer risk in patients with lung nodules identified by imaging is approximately $1.9 billion in the United States and $3.9 billion for both the U.S. and European Union. Veracyte also plans to explore opportunities to deploy its "field of injury" technology at other points along the lung cancer care continuum. The company believes the overall global lung cancer diagnostic market is approximately $30 billion.

About Lung Cancer

Lung cancer is the deadliest cancer globally, killing more than 1.75 million people worldwide each year. Early detection is key, with a five-year survival rate of over 60 percent when the cancer is found early, compared to five percent when it is found at a later stage. Lung nodules are typically the first sign of lung cancer. Approximately two million lung nodules are detected each year in the U.S. While the vast majority of lung nodules ultimately prove to be benign, physicians currently lack clear diagnostic tools to determine which patients have cancer and which do not. This can lead to unnecessary invasive biopsies, which are costly and risky, as well as to delayed diagnosis and treatment.

Conference Call and Webcast Details

Veracyte will host a conference call and webcast today at 5:00 p.m. Eastern Time to discuss the company's third quarter 2019 financial results and provide a general business update, including details on the new nasal swab test data for early lung cancer detection. The conference call will be webcast live from the company's website and will be available via the following link: https://edge.media-server.com/mmc/p/djat9cqg.

The webcast should be accessed 10 minutes prior to the conference call start time. A replay of the webcast will be available for one year following the conclusion of the live broadcast and will be accessible on the company's website at https://investor.veracyte.com/events-presentations.

The conference call can be accessed as follows:
U.S./Canada participant dial-in number (toll-free): (855) 541-0980
International participant dial-in number: (970) 315-0440
Conference I.D.: 8767084

About Veracyte

Veracyte (Nasdaq: VCYT) is a leading genomic diagnostics company that improves patient care by providing answers to clinical questions that inform diagnosis and treatment decisions without the need for costly, risky surgeries that are often unnecessary. The company's products uniquely combine RNA whole-transcriptome sequencing and machine learning to deliver results that give patients and physicians a clear path forward. Since its founding in 2008, Veracyte has commercialized seven genomic tests and is transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis. Veracyte is based in South San Francisco, California. For more information, please visit www.veracyte.com and follow the company on Twitter (@veracyte).

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, the ability of our nasal swab test to allow early detection of lung cancer, the reliability of our nasal swab test compared to other methods of diagnosis, and the total addressable market for our nasal swab test. Forward-looking statements are neither historical facts nor assurances of future performance, but are based only on our current beliefs, expectations and assumptions. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to: our ability to achieve milestones under the collaboration agreement with Johnson & Johnson; our ability to achieve and maintain Medicare coverage for our tests; the benefits of our tests and the applicability of clinical results to actual outcomes; the laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; our ability to successfully achieve and maintain adoption of and reimbursement for our products; the amount by which use of our products are able to reduce invasive procedures and misdiagnosis, and reduce healthcare costs; the occurrence and outcomes of clinical studies; and other risks set forth in our filings with the Securities and Exchange Commission, including the risks set forth in our quarterly report on Form 10-Q for the quarter ended June 30, 2019. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

*****Johnson & Johnson Services, Inc. is the legal entity party to the agreement.

NOTE TO EDITORS: To view animation video showing how the Veracyte nasal swab test works, click here.

View source version on businesswire.com: https://www.businesswire.com/news/home/20191022005454/en/

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