May 19, 2021

Veracyte Announces New Pivotal Clinical Validation Data at ASCO Showing Noninvasive Nasal Swab Test Can Significantly Improve Early Lung Cancer Detection

Company to hold webcast to discuss findings on Thursday, May 20, at 10:00 a.m. ET

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 19, 2021-- Veracyte, Inc. (Nasdaq: VCYT) today announced pivotal clinical validation data showing that the company's noninvasive nasal swab test can significantly improve the early assessment of lung cancer. The new findings show that the Percepta Nasal Swab, a first-of-its-kind genomic test, accurately classifies lung cancer risk in current or former smokers with lung nodules so that those with benign nodules may safely avoid unnecessary additional procedures, while those with likely cancerous nodules may receive more timely diagnosis and treatment. The findings will be presented June 4, 2021 at the American Society of Clinical Oncology (ASCO) Annual Meeting.

"Lung nodules are often the first sign of lung cancer and cannot be ignored, yet most of them are benign," said Carla R. Lamb, M.D., interventional pulmonologist at Lahey Hospital & Medical Center in Burlington, Mass., who was an investigator on the nasal classifier study. "Today, physicians have limited objective tools to determine which patients with lung nodules found on CT scans have cancer and which don't. Our findings showed that the nasal swab test can determine, with a high level of accuracy, which patients are at low risk of cancer and can avoid invasive procedures. Similarly, it can identify which patients are at high risk and may be confidently directed to further work-up and, potentially, to the treatment they need. An objective tool that can accurately inform these decisions could be a game-changer for early lung cancer assessment."

For the study, researchers evaluated the performance of the nasal swab test on a blinded, independent validation set of 249 patients from multiple cohorts of prospectively collected nasal samples of current or former smokers undergoing evaluation for lung nodules found on computed tomography (CT). All were followed for up to one year or until physicians made a final, adjudicated diagnosis. The cancer prevalence in the validation cohort was 54% -- higher than the 25% cancer prevalence expected in the broad population of patients with suspicious nodules, on which the test is expected to be used.

Results of the validation study demonstrate that the test identifies patients as low risk for cancer with a sensitivity of 96.3% (CI: 91.6%-98.4%) and specificity of 41.7% (CI: 33.1%-50.9%). At the same time, the test identifies patients as high risk for cancer with a specificity of 90.4% (CI: 83.68%-94.57%) and sensitivity of 58.2% (CI: 49.74%-66.22%). These findings show the test classifies more than 40% of patients with confirmed benign nodules as low risk, allowing them to avoid further procedures, and it classifies nearly 60% with confirmed malignant nodules as high risk, enabling them to be directed to more timely diagnosis and potential treatment. The remaining patients were classified as intermediate risk for cancer.

When the test's performance was applied to a population with 25% cancer prevalence, it showed that the test's negative predictive value (NPV) is 97.1%, which means that a patient classified as low risk has only a 2.9% risk of malignancy. Similarly, the positive predictive value (PPV) is 67%, meaning that nearly 70% of patients classified as high risk will have lung cancer. The American College of Chest Physicians' current guidelines recommend diagnostic biopsy for patients with more than 65% cancer risk.

"What is really exciting about these data is that doctors will be able to tell their patients with suspicious lung nodules that they are low risk for cancer and can likely avoid further work-up, with very high certainty that they have not missed a cancer," said Giulia C. Kennedy, Ph.D., Veracyte's chief scientific officer and chief medical officer. "At the same time, they can be confident in guiding patients who are high risk to further diagnostic procedures, in line with current guidelines. These findings suggest that the Percepta Nasal Swab test will be able to objectively and accurately stratify approximately half of the patients with lung nodules found on CT scans to low or high risk, while those not classified will remain a candidate for current standard of care. We are excited about the opportunity to transform the early assessment of lung nodules with a simple nasal swab test."

The Percepta Nasal Swab test uses advanced genomic and established "field of injury" technology to detect smoking-related damage associated with lung cancer in current or former smokers using a sample collected from the nasal passage. Veracyte developed the final classifier using RNA whole-transcriptome sequencing and machine learning on a rich training set of nasal samples from more than 1,100 patients representing a wide range of lung and tumor biology.

Veracyte expects to begin making the Percepta Nasal Swab test available to a select number of sites in the second half of 2021. The company aims to adapt the test on the nCounter Analysis System in 2022, enabling its expansion to physicians and their patients in global markets in 2023.

The Percepta Nasal Swab test is a key part of Veracyte's comprehensive lung cancer portfolio, which aims to transform care at every step of the patient journey. Collectively, the company's tests are leveraging cutting-edge genomic science and technology to provide answers and insights that enable physicians and patients to make better, faster and more confident care decisions. The lung cancer portfolio includes the Percepta Genomic Sequencing Classifier, which helps improve lung cancer diagnosis when bronchoscopy results are inconclusive, and the in-development Percepta Genomic Atlas, which is intended to detect gene alterations that may inform lung cancer treatment decisions, using the same small biopsy that was collected for diagnosis.

Development and validation of the Percepta Nasal Swab test is part of Veracyte's ongoing collaboration with the Lung Cancer Initiative at Johnson & Johnson.*

Conference Call and Webcast Details

Veracyte will host a conference call and webcast on Thursday, May 20, at 10:00 a.m. Eastern Time to discuss the Percepta Nasal Swab test data. 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/upf4ko9q. 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.:	4216318

About Lung Cancer

Lung cancer kills more than 1.8 million people worldwide each year.[i] Early detection is key, with a five-year survival rate of nearly 60 percent when the cancer is found early, compared to 6 percent when it is found at a later stage.[ii] Lung nodules are typically the first sign of lung cancer, but most lung nodules are benign. Each year in the U.S., an estimated 1.6 million lung nodules are found incidentally on CT scans and, with recently expanded recommendations from the U.S. Preventive Services Task Force, an estimated 15 million Americans are eligible for annual lung cancer CT screening. Physicians currently lack objective tools to determine which lung nodules found on CT are benign and which are cancerous.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global genomic diagnostics company that improves patient care by providing answers to clinical questions, informing diagnosis and treatment decisions throughout the patient journey in cancer and other diseases. The company's growing menu of genomic tests leverage advances in genomic science and technology, enabling patients to avoid risky, costly diagnostic procedures and quicken time to appropriate treatment. The company's tests in lung cancer, prostate cancer, breast cancer, thyroid cancer, bladder cancer and idiopathic pulmonary fibrosis are available to patients and its lymphoma subtyping and renal cancer tests are in development. With Veracyte's exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its tests to patients worldwide. 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, including, but not limited to, our statements related to our plans, objectives, expectations (financial and otherwise) or intentions with respect to the Percepta Nasal Swab test. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "suggest," "may," "will" and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. Examples of forward-looking statements include, among others, statements regarding Veracyte's belief that its Percepta Nasal Swab test can significantly improve the early assessment of lung cancer and assist health care providers in guiding patients regarding treatment options. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to: Veracyte's ability to achieve and maintain Medicare coverage for its tests; the benefits of Veracyte's tests and the applicability of clinical results to actual outcomes. Additional factors that may impact these forward-looking statements can be found under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the SEC on February 22, 2021 and our subsequent quarterly reports on Form 10-Q. A copy of these documents can be found at the Investors section of our website at www.veracyte.com. The risks and uncertainties may be amplified by the COVID-19 pandemic, which has caused significant economic uncertainty. The extent to which the COVID-19 pandemic impacts Veracyte's businesses, operations, and financial results, including the duration and magnitude of such effects, will depend on numerous factors, which are unpredictable, including, but not limited to, the duration and spread of the outbreak, its severity, the actions to contain the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume. These forward-looking statements speak only as of the date hereof and, except as required by law, 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.

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

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[i] World Health Organization
[ii] American Lung Association

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