Clinical Validation Data Published in CHEST Demonstrate that Veracyte's Percepta Nasal Swab Test Improves Lung Cancer Risk Assessment for Patients with Lung Nodules

November 29, 2023

Non-invasive genomic test is designed to help physicians guide next steps for current and former smokers with lung nodules

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 29, 2023-- Veracyte, Inc. (Nasdaq: VCYT) announced that clinical validation data published in the journal *CHEST* show that the company's Percepta Nasal Swab test determines lung cancer risk, with high accuracy, among people who currently smoke or have previously smoked and have lung nodules. The findings suggest that the novel, non-invasive genomic test can help physicians guide next steps for these patients, enabling them to potentially avoid unnecessary invasive procedures or accelerate time to appropriate treatment.

Lung cancer is the leading cause of cancer death worldwide. Lung nodules are an early indicator of lung cancer and are typically found using computed tomography (CT) scans. In the United States, approximately 15 million people are eligible for annual lung cancer screening with low-dose CT scans based on their smoking history and other factors and currently an estimated 1.6 million lung nodules are found incidentally each year in patients being evaluated with a CT scan for an unrelated condition. While most lung nodules are not cancerous, their detection can result in unnecessary diagnostic procedures and anxiety for patients. At the same time, early detection of cancerous nodules can lead to better patient outcomes.

"Physicians need an objective, accurate tool to help guide care for patients when a lung nodule is found on a CT scan," said Bill Bulman, M.D., Veracyte's medical director for Pulmonology and an author on the *CHEST* manuscript. "Our findings reinforce the ability of the Percepta Nasal Swab test to improve risk assessment of lung nodules and help avoid unnecessary diagnostic procedures for those at low risk of cancer while supporting timely diagnosis and treatment for those with high risk of cancer."

Veracyte's Percepta Nasal Swab test is a simple, non-invasive genomic test that can be done in the physician's office and is designed to assess lung cancer risk in patients who currently smoke or have previously smoked and have lung nodules found on CT scans. The test reports whether a patient has a high-, moderate- or low-risk for lung cancer, providing insights to help physicians objectively determine which patients with lung nodules to work up for lung cancer and which patients to simply monitor with imaging.

For the *CHEST* study, researchers used the Percepta Nasal Swab test, which was trained on a cohort of 1,120 patients with lung nodules that were either malignant or benign, to evaluate nasal samples from an independent cohort of 312 eligible patients followed for at least 12 months or until a final diagnosis of benign or malignant was determined.

Results show that the Percepta Nasal Swab test is highly accurate in identifying patients with low-risk nodules (97% sensitivity, with 40% specificity). This high sensitivity provides a negative predictive value, or NPV, of 98% in a population with a 25% cancer prevalence, meaning the test could assist physicians in avoiding unnecessary invasive procedures in patients with a benign nodule, with a very small risk of missing a cancer.

Similarly, researchers found that the test is highly accurate in identifying patients with high-risk nodules (92% specificity, with 57% sensitivity). This high specificity provides a positive predictive value, or PPV, of 70% in a population with a 25% cancer prevalence, meaning the test could assist physicians in directing these patients to further procedures so they could obtain an accurate diagnosis and speed time to treatment, if necessary.

The Percepta Nasal Swab test had consistently high performance across various groups of patients within the study cohort, including those with prior cancers and different lung cancer subtypes, lung nodule sizes (including nodules <8 mm), smoking histories and lung cancer screening eligibility, suggesting the test's potential clinical value in a wide range of patients. In contrast, currently available physician risk calculators were developed with specific patient populations in mind and tend to perform unevenly across different types of patients.

"We believe our Percepta Nasal Swab test can be paradigm-changing in the evaluation of lung cancer risk among patients with lung nodules," said Dr. Bulman. "By helping to guide next steps for physicians and their patients, we aim to help make lung nodule evaluation, including through lung cancer screening programs, more efficient and effective."

Publication of the Percepta Nasal Swab test clinical validation study is an important step in Veracyte's journey toward securing payer reimbursement for the test, prior to the test being made widely available. Additionally, the company is currently conducting a prospective clinical utility study, known as NIGHTINGALE, at hospitals and clinics around the United States to demonstrate the test's ability to improve patient care and outcomes.

The Percepta Nasal Swab test was developed with RNA whole-transcriptome sequencing and machine-learning technology. It utilizes foundational "field of injury" science, which evaluates genomic changes associated with lung cancer that can be found in epithelial cells in the nasal passages of current and former smokers.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company whose vision is to transform cancer care for patients all over the world. We empower clinicians with the high-value insights they need to guide and assure patients at pivotal moments in the race to diagnose and treat cancer. Our high-performing tests enable clinicians to make more confident diagnostic, prognostic, and treatment decisions for some of the most challenging diseases such as thyroid, prostate, breast, bladder and lung cancers, as well as interstitial lung diseases. We help patients avoid unnecessary procedures and speed time to diagnosis and appropriate treatment. In addition to making our tests available in the U.S. through our central laboratories, we also aim to deliver our tests to patients worldwide through a distributed model to laboratories that can perform them locally. 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 our clinical tests in and outside of the United States. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "positioned," "designed" and similar

references to future periods. Examples of forward-looking statements include, among others, that the Percepta Nasal Swab test can help physicians guide next steps for patients who currently smoke or have previously smoked and have lung nodules, enabling them to potentially avoid unnecessary invasive procedures or accelerate time to appropriate treatment; the Percepta Nasal Swab Test can potentially help those who are low risk avoid unnecessary diagnostic procedures, including surgery, while supporting timely treatment for those who have the disease; and the Percepta Nasal Swab test may help make lung nodule evaluation more efficient and effective. 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 on February 22, 2023, and our Quarterly Report on Form 10-Q filed for the three months ended September 30, 2023. Copies of these documents, when available, may be found in the Investors section of our website at https://investor.veracyte.com. These forward-looking statements speak only as of the date hereof and, except as required by law, we specifically disclaim 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.

Veracyte, the Veracyte logo and Percepta are registered trademarks of Veracyte, Inc. and its subsidiaries in the U.S. and selected countries.

View source version on businesswire.com: https://www.businesswire.com/news/home/20231129259153/en/

Investors:
Shayla Gorman
Director, Investor Relations
investors@veracyte.com
619-393-1545

Media:
Tracy Morris
Vice President of Global Corporate Communications
tracy.morris@veracyte.com
650-380-4413

Source: Veracyte, Inc.