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Veracyte Announces New Expanded Data at CHEST Underscoring Percepta Nasal Swab Test's Ability to Improve Early Lung Cancer Assessment

Company begins making novel, noninvasive test available to limited number of clinical sites to support more timely, accurate lung nodule diagnosis

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 11, 2021-- Veracyte, Inc. (Nasdaq: VCYT) today announced that new expanded clinical validation data reinforce the ability of the company's noninvasive Percepta Nasal Swab test to help physicians more accurately assess lung cancer risk in patients with lung nodules. The findings also show that the test delivers strong clinical performance across different nodule sizes and cancer stages in current or former smokers, and for patients who have already had other cancer(s).

The new data underscore the Percepta Nasal Swab test's ability to help physicians more accurately, quickly and confidently determine which patients with lung nodules found on computerized tomography (CT) scans may avoid unnecessary invasive procedures and which should proceed to diagnostic work-ups and obtain treatment if necessary. The findings will be shared in an oral presentation at the 2021 American College of Chest Physicians (CHEST) Annual Meeting, which is being held virtually October 17-20, 2021. Veracyte also announced it has begun making the Percepta Nasal Swab test available to a limited number of clinical sites as it builds the clinical utility data to support reimbursement.

"Approximately 15 million patients are now recommended for annual lung cancer CT screening and about 1.6 million lung nodules are found incidentally," said Carla R. Lamb, M.D., interventional pulmonologist at Lahey Hospital & Medical Center in Burlington, Mass., who will present the new data. "Today, physicians have limited objective tools to help accurately determine which patients with lung nodules found on CT scans have cancer and which don't. This uncertainty can lead to unnecessary diagnostic procedures or to potentially delayed diagnosis and treatment. Our findings reinforce the Percepta Nasal Swab test's ability to more accurately identify patients as low, moderate or high risk for lung cancer so that physicians can make more confident decisions about next steps for their patients."

The Percepta Nasal Swab test's robust performance in classifying lung cancer risk was previously demonstrated in a blinded, independent validation set of 249 patients from multiple cohorts comprising prospectively collected nasal samples. All patients were current or former smokers undergoing evaluation for lung nodules found on CT scans. Patients were followed for up to one year or until physicians made a final, adjudicated diagnosis. The new expanded data being presented at this year's CHEST meeting include 63 additional patients with prior (non-lung) cancers who were part of a planned secondary endpoint analysis.

In the expanded cohort of 312 patients, when the Percepta Nasal Swab test identified patients as low risk, its sensitivity was 97%, providing a negative predictive value (NPV) of 98% in a population with the 25% cancer prevalence that would be expected in a broad cohort with suspicious lung nodules. This NPV would assist physicians in avoiding unnecessary invasive procedures in these patients with a very small likelihood of missing a cancer. When the test identified patients as high risk, its specificity was 92%, for a positive predictive value (PPV) of 70% at a malignancy rate of 25%. This PPV would assist physicians in directing these patients to further procedures so they could obtain an accurate diagnosis and speed time to treatment if necessary. Patients in the moderate risk group could be managed according to current clinical guidelines.

In a sub-analysis of the expanded validation set, researchers found that the Percepta Nasal Swab test's performance is strong across different nodule sizes, with the test identifying 67% of cancers in nodules below 8 mm as moderate risk, while labeling 100% of malignant nodules greater than or equal to 8 mm as high or moderate risk. Performance was also consistent across all stages of non-small cell lung cancer (NSCLC), with 100% of NSCLC Stage II or greater cancers labeled as moderate or high risk.

"These findings suggest that the Percepta Nasal Swab test will provide significant clinical utility across a range of lung nodule sizes and lung cancer stages," said Giulia C. Kennedy, Ph.D., Veracyte's chief scientific officer and chief medical officer. "We are excited to begin offering the test to sites as part of our clinical utility study and to transform lung cancer early assessment so that more unnecessary procedures can be avoided and more lives can be saved."

Also at the CHEST meeting, real-world data will be presented demonstrating that the Percepta Genomic Sequencing Classifier (GSC) can help reduce unnecessary surgeries and guide next steps in lung cancer evaluation for patients with suspicious lung nodules whose bronchoscopy results were inconclusive. In one retrospective clinical utility study, researchers from the Medical College of Wisconsin found that the Percepta GSC reclassified one-third of lung nodules with indeterminate bronchoscopy results as either low risk or high risk. Similarly, researchers from AnMed Health Medical Center in Anderson, South Carolina, found that the Percepta GSC enabled more than half of patients' indeterminate lung nodules to be reclassified and, among those moved to a low risk category, there was a significant reduction in the rate of invasive follow-up procedures.

The Percepta Nasal Swab test and GSC use advanced genomic technology to detect smoking-related damage associated with lung cancer in the respiratory tract of current or former smokers. Both tests are 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. Veracyte's lung cancer portfolio also includes 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.

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.[i] 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 accurately determine which lung nodules found on CT are benign and which are cancerous.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global 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 diagnostic tests leverages 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, colon cancer and idiopathic pulmonary fibrosis are available to patients and its renal cancer and lymphoma subtyping tests are in development, the latter as a companion diagnostic. 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 and Percepta Genomic Sequencing Classifier. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "suggest," "may," "will" "prospective" 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 healthcare providers in guiding patients regarding treatment options. 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. 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.

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

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