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Veracyte Announces Clinical Data Demonstrating Clinical Validity and Utility of Percepta Classifier in Lung Cancer Diagnosis When Bronchoscopy Results Are Inconclusive

Data Being Presented at CHEST Annual Meeting 2019

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 21, 2019-- Veracyte, Inc. (Nasdaq: VCYT) today announced data demonstrating the clinical validity of its next-generation Percepta® Genomic Sequencing Classifier (GSC) and the clinical utility of its first-generation test in a real-world setting in improving lung cancer diagnosis when bronchoscopy results are inconclusive. The findings will be presented on Thursday, October 23, at the annual meeting of the American College of Chest Physicians® (CHEST) in New Orleans.

“These data confirm the performance of our Percepta classifier and its ability to guide care for lung nodule patients when bronchoscopy findings are inconclusive,” said Bonnie H. Anderson, Veracyte’s chairman and chief executive officer. “We have been especially pleased by physicians’ positive response to our next-generation Percepta GSC, which we introduced in June of this year and which provides expanded information to physicians.”

For the first study, researchers prospectively validated the Percepta GSC on a blinded, independent set of 412 samples from patients with lung nodules that were referred for bronchoscopy evaluation. Among a subset of patients with low or intermediate pre-test risk for whom malignancy was confirmed, the Percepta GSC significantly improved sensitivity for lung cancer detection in combination with bronchoscopy (95.5 percent), compared to bronchoscopy alone (40.9 percent). The genomic classifier demonstrated improved sensitivity compared to bronchoscopy regardless of nodule size or location or cancer subtype.

Among a subset of 188 patients with an intermediate pre-test risk of cancer, which account for the majority of lung nodules, the Percepta GSC demonstrated high accuracy when it down-classified patients to “low risk” for cancer (negative predictive value of 91 percent). The test also had a positive predictive value of 65 percent when it up-classified patients to “high risk” for cancer. The American College of Chest Physicians recommends that patients with a low risk of cancer undergo monitoring with CT imaging and that patients with a cancer risk of 65 percent or greater undergo surgical treatment.

“Bronchoscopy is often used to evaluate potentially cancerous lung nodules because it offers a nonsurgical way to detect lung cancer. However, bronchoscopy results are often inconclusive, which leaves physicians with a dilemma of whether to direct the patient for more invasive procedures or just monitor them with imaging at the risk of missing a cancer,” said Giulia C. Kennedy, Ph.D., chief scientific officer and chief medical offer for Veracyte, who was a researcher in the study. “Our findings suggest that use of the Percepta GSC can improve the performance of bronchoscopy, making it a potentially more useful diagnostic tool that can help lung nodule patients at low risk for cancer avoid unnecessary invasive procedures or those at high risk get more timely treatment.”

The next-generation Percepta GSC was developed on Veracyte’s RNA whole-transcriptome sequencing and machine learning platform and is based on novel “field of injury” science – which identifies genomic changes associated with lung cancer in current or former smokers using a simple brushing of the person’s airway. The test is performed on a sample from the patient’s main lung airway, which is collected during a bronchoscopy. Veracyte estimates that approximately 360,000 bronchoscopies are currently performed each year to evaluate suspicious lung nodules for cancer and that up to 60 percent of these produce inconclusive results.

A second, independent study is being presented at the CHEST meeting by researchers from LAC+USC Medical Center, a county hospital in Los Angeles, on their experience using the original Percepta classifier.

Lung cancer is the leading cause of cancer deaths worldwide. In the United States, lung cancer causes more than 154,000 deaths each year – more than the next three most prevalent cancers combined. Because lung cancer is difficult to diagnose before it has metastasized, only 16 percent of cases are detected at an early stage, when the disease is more treatable. Lung cancer’s five-year survival rate is only 18 percent, much lower than that of other common cancers. Approximately 80 percent of lung cancer deaths are caused by smoking.

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 Percepta to improve the diagnosis of lung cancer. 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.

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