Veracyte Announces Presentation of “Real World” Clinical Utility Data at CHEST 2018 Showing Percepta Classifier Reduces Invasive Procedures in Lung Cancer Diagnosis

Preliminary data from ongoing, three-year registry study demonstrate that reduction in potentially harmful invasive procedures extends for first 12 months post-test

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 9, 2018-- Veracyte, Inc. (Nasdaq: VCYT) announced that new interim data from a three-year, “real world,” prospective clinical utility study show that use of the Percepta Bronchial Genomic Classifier to evaluate patients with potentially cancerous lung nodules reduced invasive procedures during 12 months of patient follow-up. The early findings were presented in an oral session at CHEST 2018, the annual meeting of the American College of Chest Physicians®; being held October 6-10 in San Antonio, Texas.

The ongoing 40-site registry trial aims to measure the impact of the Percepta test on lung nodule management in “real world” clinical practice and to monitor clinical outcomes of patients managed with the test. Reviewing results from the first 258 evaluable patients, researchers found that patients who had a negative Percepta result following an inconclusive bronchoscopy had lower rates of subsequent invasive procedures at all evaluation time points (immediately post-test, 3 months, 6 months and 12 months), compared to physicians’ plans for these patients prior to Percepta testing. At 12 months of follow-up, researchers observed a 20 percent relative reduction in invasive procedures as compared to physicians’ initial plans.

The findings also showed that Percepta classifier results changed how physicians managed patients with lung nodules. The researchers found that patients with negative Percepta test results were significantly less likely to undergo invasive procedures at all time points over the 12-month post-test period, as compared to patients with positive genomic test results.

“Physicians often use bronchoscopy to evaluate potentially cancerous lung nodules, but the results from this procedure are often inconclusive, which can lead to unnecessary, invasive follow-up procedures for a diagnosis,” said Giulia C. Kennedy, Ph.D., chief scientific and medical officer at Veracyte. “These early data show that use of the Percepta test following an inconclusive bronchoscopy result can reduce the number of unnecessary procedures and that this trend is durable over 12 months of follow-up.”

The Percepta classifier uses proprietary “field of injury”-based technology to detect genomic changes associated with lung cancer in the main lung airway of current and former smokers. Percepta detects these genomic changes to determine the likelihood that a nodule is cancerous without the need to sample the nodule directly. Clinical validation data published in The New England Journal of Medicine demonstrated the Percepta test’s high accuracy in identifying patients at low risk of lung cancer (negative predictive value of 91 percent), suggesting that these patients may safely avoid further invasive procedures.

“These new data reinforce the value that the Percepta classifier brings to lung cancer diagnosis by reducing, over the long term, the number of invasive procedures among patients being evaluated for suspicious lung nodules,” said Bonnie Anderson, Veracyte’s chairman and chief executive officer. “We believe these findings support physicians’ use of the Percepta classifier as a complement to diagnostic bronchoscopy and look forward to sharing future findings from our ongoing registry trial.”

The Percepta multicenter registry study has enrolled over 655 patients who were former or current smokers without prior active cancer and who were deemed eligible for bronchoscopy following identification of a pulmonary lesion on CT scan. Physicians captured a bronchial brushing at the time of the bronchoscopy to enable genomic diagnostic evaluation by the Percepta classifier if the bronchoscopy result was inconclusive.

Lung cancer is the leading cause of cancer-related deaths in the United States, killing over 154,000 Americans each year, according to the American Cancer Society. Early detection and diagnosis can significantly improve survival, but currently very few lung cancer cases (just 16 percent) are diagnosed at an early stage when the disease is most treatable. The identification of a lung nodule or lesion on a CT scan – either through screening or incidentally – is often the first sign that an individual may have lung cancer. Determining whether lung nodules or lesions identified on CT scans – either through screening or incidentally – are cancerous is often difficult, which can lead to patients undergoing invasive, risky and expensive procedures that are frequently unnecessary.

About Percepta

The Percepta Bronchial Genomic Classifier uses advanced genomic and machine learning technology to improve lung cancer diagnosis for patients while reducing the need for invasive procedures. The classifier is run when bronchoscopy results are inconclusive, and helps physicians determine which patients are at low or very low risk for cancer and may therefore be monitored with CT scans instead of undergoing further, invasive diagnostic procedures. The Percepta classifier uses proprietary “field of injury”-based technology to detect molecular changes in the main lung airway of current or former smokers. Percepta detects these genomic changes to determine the likelihood that a nodule is cancerous without the need to sample the nodule directly. The classifier’s performance has been validated in multiple, rigorous clinical studies, including clinical validation data published in The New England Journal of Medicine.

About Veracyte

Veracyte (Nasdaq: VCYT) is a leading genomic diagnostics company that improves patient care by providing trustworthy and actionable answers to challenging clinical questions. The company’s products uniquely combine advanced genomic technology, clinical science and machine learning to provide answers that give physicians and patients a clear path forward, informing both diagnosis and treatment decisions without the need for costly, risky surgeries that are often unnecessary. Since its founding in 2008, Veracyte has commercialized three genomic tests, which are transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis and collectively target a $2 billion market opportunity. 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, our belief that our genomic tests will transform the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis; statements regarding the ability of the Percepta Bronchial Genomic Classifier to reduce unnecessary invasive procedures in lung cancer diagnosis; and statements regarding the ability of the Envisia Genomic Classifier to improve IPF diagnosis. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Forward-looking statements involve risks and uncertainties, which could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: our ability to achieve Medicare coverage for our tests, the market opportunity for the Envisia classifier, the benefits of our tests, 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 sell our Afirma tests and successfully transition to our next-generation Afirma GSC; 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, 2018. 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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