Veracyte Announces New Real-World Data Reinforcing the Potential Clinical Value of Percepta and Envisia Classifiers to Improve Diagnosis of Serious Lung Diseases

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ePosters presented during ATS 2020 Virtual conference

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 5, 2020--

Veracyte, Inc. (Nasdaq: VCYT) announced today that data presented at the American Thoracic Society 2020 Virtual conference reinforce the potential clinical value of the company's advanced genomic tests in diagnosing serious lung diseases. The data, presented in three ePosters, demonstrate how Veracyte's Percepta Genomic Sequencing Classifier and Envisia Genomic Classifier may improve upon the diagnostic standard of care in lung cancer and idiopathic pulmonary fibrosis (IPF), respectively.

Lung cancer is the leading cause of cancer deaths, and will kill approximately 136,000 Americans this year – more than the next three leading cancers combined. Lung nodules are typically the first sign of lung cancer, however, determining which lung nodules are cancerous and which are benign is often challenging, leading to unnecessary invasive procedures or delayed treatment.

Veracyte's Percepta GSC helps guide next steps when bronchoscopy results are inconclusive. Patients deemed low-risk for cancer by the test can be monitored and those who are high-risk can proceed to further work-up.

In a study presented at ATS 2020, researchers evaluated the sensitivity of bronchoscopy alone, the Percepta GSC, and the Percepta GSC combined with bronchoscopy in detecting malignant lung nodules among 44 patients with low or intermediate pre-test risk of cancer. The overall sensitivity of bronchoscopy alone was 40.9 percent, compared to 92.3 percent for the Percepta GSC and 95.5 percent for bronchoscopy and the classifier combined.

"These findings suggest that the Percepta GSC substantially increases the sensitivity of bronchoscopy in detecting cancer among lung nodules that are indeterminate following clinical work-up," said Travis Dotson, M.D., associate professor, Wake Forest Baptist Health, who presented the data. "This enhanced diagnostic capability can help physicians more confidently determine which patients need further diagnostic procedures and which can simply be monitored over time."

In two additional ATS 2020 ePoster presentations, researchers shared data from two prospective studies evaluating Veracyte's Envisia Genomic Classifier in the diagnosis of IPF. Each year in the United States and Europe, up to 220,000 patients are evaluated for suspected interstitial lung diseases (ILDs), including IPF, which is among the most common, deadly and difficult to diagnose of these lung-scarring diseases

The Envisia classifier is the first commercially available genomic test that helps distinguish IPF from other ILDs without the need for risky surgery. The classifier distinguishes the usual interstitial pneumonia (UIP) pattern, the hallmark lung pattern of IPF, and thereby enables physicians to more confidently diagnose IPF when results from high-resolution CT (HRCT) imaging are not definitive. Veracyte is preparing to launch the test in global markets in late 2021.

Findings from the two Envisia classifier studies presented at ATS 2020, both of which utilized patient cohorts from the BRAVE (Bronchial Sample Collection for a Novel Genomic Test) study, reinforce the clinical validity and utility of the classifier. The data from these studies, which were also published online recently in the *American Journal of Respiratory and Critical Care Medicine*, show that the genomic test detects UIP with high accuracy (92.1 percent specificity and 60.3 percent sensitivity). Additionally, the findings suggest that the Envisia classifier improves the diagnostic accuracy of high-resolution CT (HRCT) imaging. Researchers reported that, among a cohort of 85 BRAVE patients, HRCT alone identified UIP with a sensitivity of 34 percent. Combining Envisia classifier results with HRCT more than doubled this sensitivity for detecting UIP – from 34 to 79.2 percent.

"These results demonstrate that the Envisia Genomic classifier can improve upon standard of care for IPF diagnosis, enabling physicians to diagnose the disease less invasively and with more confidence," said Amy Hajari Case, M.D., Piedmont Physicians. "This is meaningful, because it enables patients to more quickly receive appropriate treatment for this progressive disease."

"Collectively, the data presented at ATS 2020 provide additional clinical evidence that the Percepta and Envisia classifiers can improve the diagnosis of lung cancer and IPF," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "Supporting more effective and efficient care has become even more important in the current healthcare landscape and we believe will help fuel further physician adoption and payer reimbursement for our tests."

The following ATS 2020 ePosters can be viewed at the links below. The presentations are available on demand to ATS conference registrants through November 10:

Title: Performance of the Percepta Genomic Sequencing Classifier (GSC) as a Complement to Bronchoscopy for Indeterminate Lung Nodules (FNAs)
Presenter: Travis Dotson, M.D., Wake Forest Baptist Health
ePoster # A5948

Title: A Follow-On Prospective Clinical Validation of the Envisia Genomic Classifier
Presenter: Mary Beth Scholand, M.D., University of Utah School of Medicine
ePoster #: A2557

Title: Performance and Clinical Utility of the Genomic Classifier (Envisia) for Usual Interstitial Pneumonia in Conjunction with Local Radiology
Presenter: Amy Hajari Case, M.D., Piedmont Physicians
ePoster # A2580

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 thyroid cancer, lung cancer, breast cancer and idiopathic pulmonary fibrosis are available to patients and its lymphoma subtyping test is 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" 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, statements regarding Veracyte's belief that its Percepta and Envisia tests provide clinical value that help physicians diagnose lung cancer and IPF and its ability to deliver genomic diagnostics tests throughout the world on its distributed instrument platform. 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: the impact of COVID-19 on Veracyte's business and operating results, specifically, and the healthcare system and economy more generally, 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; the laws and regulations applicable to Veracyte's business, including potential regulation by the Food and Drug Administration or other regulatory bodies; Veracyte's ability to successfully achieve and maintain adoption of and reimbursement for its products; the amount by which use of Veracyte's 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 Veracyte's filings with the Securities and Exchange Commission, including the risks set forth in its quarterly report on Form 10-Q for the quarter ended June 30, 2020. 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.

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