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Veracyte Unveils Next-Generation Percepta Genomic Sequencing Classifier for Improved Lung Cancer Diagnosis

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 20, 2019-- Veracyte, Inc. (Nasdaq: VCYT), a leading genomic diagnostics company, today announced new data demonstrating that its next-generation Percepta® Genomic Sequencing Classifier (GSC) provides expanded lung cancer risk information that can further guide next steps for patients with lung nodules.

Researchers prospectively validated the Percepta GSC on 412 patients with lung nodules who had inconclusive results following bronchoscopy, a common nonsurgical procedure to diagnose lung cancer. Among patients with an “intermediate” pre-test risk of cancer – the group that accounts 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 (PPV) of 65 percent when it up-classified patients to “high risk” for cancer. The American College of Chest Physicians recommends patients with a cancer risk of 65 percent or greater undergo surgical treatment.

The new findings will be shared this evening at a company event being held during the American Thoracic Society 2019 International Conference(ATS 2019) in Dallas.

“Determining whether lung nodules are benign or cancerous is often difficult, which can lead to unnecessary invasive procedures and treatment delays,” said Giulia C. Kennedy, Ph.D., chief scientific and medical officer of Veracyte. “With its ability to both down-classify and up-classify patients with inconclusive lung nodules, the Percepta GSC should help physicians avoid invasive biopsies in patients who are at low risk of lung cancer, while helping to guide intervention steps for those at high risk.”

The Percepta GSC utilizes 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 also Veracyte’s third clinical classifier to be developed on the company's novel RNA whole-transcriptome sequencing and machine learning platform. Veracyte plans to begin making the Percepta GSC available to physicians by the middle of 2019.

“We are excited to unveil our Percepta GSC, which we believe will improve diagnosis and treatment decisions for patients undergoing evaluation for lung cancer,” said Bonnie Anderson, Veracyte’s chairman and chief executive officer. “Additionally, we believe that moving the Percepta classifier to our RNA whole-transcriptome sequencing platform – together with our Afirma and Envisia classifiers – will provide operational efficiencies and a robust foundation for continued innovation. This includes our development of the first nasal swab test for early lung cancer detection.”

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. Veracyte estimates that approximately 350,000 bronchoscopies are currently performed each year to evaluate suspicious lung nodules for cancer and that up to 70 percent of these produce inconclusive results.

Also during the ATS 2019 conference, Kevin Flaherty, M.D., of the University of Michigan Health System, will present clinical utility data demonstrating that Veracyte’s Envisia™ Genomic Classifier improves diagnosis of idiopathic pulmonary fibrosis (Session D12, Abstract A5837). These data were published online in *The Lancet Respiratory Medicine* on April 1, 2019.

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 five genomic tests, which are 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 timing by which our Percepta GSC will be made available to physicians; and our ability to achieve and maintain Medicare coverage for our tests, including the Envisia Genomic Classifier. 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 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 annual report on Form 10-Q for the quarter ended March 31, 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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