Veracyte Announces Publication of Manuscript Describing Scientific Rigor Behind Next-Generation Percepta Genomic Sequencing Classifier

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RNA sequencing and novel machine learning algorithms generate a test that improves lung cancer diagnosis using brushings from the main lung airway

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 22, 2020-- Veracyte, Inc. (Nasdaq: VCYT) today announced the publication of a manuscript detailing the development of the company's next-generation Percepta ® Genomic Sequencing Classifier (GSC), which is used to improve lung cancer diagnosis among patients with suspicious lung nodules and inconclusive bronchoscopy results. The paper, published online in *BMC Medical Genomics*, details the advanced technology used by Veracyte scientists to generate a robust genomic classifier that demonstrates diagnostic accuracy in both down- and up-classification of cancer risk, providing physicians with actionable information for many patients with inconclusive bronchoscopies.

"Bronchoscopy is commonly used to evaluate potentially cancerous lung nodules, but it often delivers inconclusive results. This frequently leads to additional diagnostic procedures, including invasive lung surgeries," said Giulia C. Kennedy, Ph.D., chief scientific officer and chief medical officer for Veracyte. "We used advanced RNA sequencing and novel machine learning technology to overcome numerous, potential confounding factors and develop a robust genomic test that improves diagnostic accuracy in lung cancer. Providing physicians with this level of actionable genomic information can reduce the number of potentially dangerous lung surgeries and help guide next intervention steps for patients."

The Percepta GSC is based on novel "field of injury" science, which identifies genomic changes that correlate with lung cancer risk in current or former smokers using a brushing to collect cells from the patient's main lung airway during a standard bronchoscopy, without the need to sample the lesion directly. Veracyte scientists developed the test using RNA whole-transcriptome sequencing and machine learning on more than 1,600 patient samples from three different cohorts. The samples are from both current and former smokers who underwent bronchoscopy for suspected lung cancer. The Percepta GSC has been commercially available since June 2019.

The *BMC Medical Genomics* paper describes how Veracyte scientists developed the Percepta GSC, mitigating multiple technical and analytical factors that could impact the classifier's performance, including demographic differences between patient cohorts, smoking status, inhaled medication use and the timing of sample collection. To account for these individual genomic and clinical features, Veracyte scientists integrated multiple classifiers, as well as a novel genomic index designed to capture the differences between current and former smokers and smoking history.

Prospective clinical validation research shows that this ensemble classification approach stabilizes the Percepta GSC's performance across patients with different clinical and genomic characteristics from multiple clinical cohorts, as well as samples from multiple RNA sequencing batches. The test classified a subset of patients with "intermediate" or "low" pre-test risk of cancer to "low" or "very low" with a high negative predictive value, potentially avoiding the need for additional invasive diagnostic procedures for these patients. The test also classified a subset of "intermediate" and "high" pre-test risk patients to "high" or "very high" risk with a high positive predictive value, which may accelerate the time to diagnosis and treatment decision.

"By utilizing cutting-edge genomic technologies and insisting on scientific rigor from development through validation, we've generated a diagnostic classifier that overcomes the many challenges of lung cancer diagnosis without the need for invasive surgery," said Bonnie Anderson, Veracyte's chairman and chief executive officer.

Lung cancer is the leading cause of cancer deaths, and is expected to kill approximately 136,000 Americans in 2020 – 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.

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 generation Percepta ® Genomic Sequencing Classifier provide clinical value that help physicians improve lung cancer diagnosis 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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