April 27, 2021

Veracyte Announces Publication of Study Showing Robust Performance of Percepta GSC in Improving Lung Cancer Diagnosis

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 27, 2021-- Veracyte, Inc. (Nasdaq: VCYT) announced today the publication of a new study that demonstrates the robust performance of the Percepta Genomic Sequencing Classifier (GSC), a novel genomic test, in helping to improve lung cancer diagnosis. The data, based on widely accepted community guidelines for establishing analytical validity, add to the growing body of clinical evidence supporting the use of the Percepta GSC to guide next steps for patients with lung nodules whose bronchoscopy results are inconclusive. The peer-reviewed paper appears online in the journal BMC Cancer.

Veracyte scientists followed criteria established by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group and the Centers for Disease Control's ACCE Project to evaluate the analytical validity of the Percepta GSC. They also assessed the Percepta GSC for reproducibility within and across laboratories.

Based on the guidelines, the scientists determined the Percepta GSC test is suitable for routine clinical use with robust analytical sensitivity, analytical specificity, and reproducibility. Expected variability in clinical laboratories — assessed in this study by using different instruments, operators, and labs — was found to be negligible.

"We are pleased to share the results of this analytical validation study, which clearly demonstrate the Percepta GSC's robust performance regardless of variations in RNA quantity, as well as the presence of blood or other contaminants, in patient samples," said Giulia C. Kennedy, Ph.D., Veracyte's chief scientific officer and chief medical officer, and an author of the study. "These findings should give physicians further confidence that the Percepta GSC can help them determine next steps for their lung-nodule patients when bronchoscopy results are inconclusive."

About the Percepta GSC

The Percepta GSC is an RNA sequencing-based risk-stratification test designed to aid patient management in cases where a lung nodule is present and bronchoscopy results are unclear. Veracyte estimates that approximately 545,000 bronchoscopies are performed each year to evaluate suspicious lung nodules and that up to 60 percent of these produce inconclusive results. 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. Previous analyses demonstrated the test's accuracy in "down-classifying" patients at low risk of lung cancer and in "up-classifying" patients at high risk of the disease. [1] The test has been commercially available since June 2019.

About Lung Cancer

Lung cancer kills more than 1.75 million people worldwide each year.[2] Early detection is key, with a five-year survival rate of nearly 60 percent when the cancer is found early, compared to six percent when it is found at a later stage.[3] Lung nodules are typically the first sign of lung cancer. 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, as well as delayed diagnosis and 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 lung cancer, prostate cancer, breast cancer, thyroid cancer, bladder cancer and idiopathic pulmonary fibrosis are available to patients and its lymphoma subtyping and renal cancer tests are 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, including, but not limited to, our statements related to our plans, objectives, expectations (financial and otherwise) or intentions with respect to the Percepta Genomic Sequencing Classifier. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "suggest," "may," "will" and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. Examples of forward-looking statements include, among others, statements regarding Veracyte's belief that its Percepta GSC test provides clinical value that helps physicians diagnose and treat lung cancer. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to: 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. Additional factors that may impact these forward-looking statements can be found under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the SEC on February 22, 2021 and our subsequent quarterly reports on Form 10-Q. A copy of these documents can be found at the Investors section of our website at www.veracyte.com. The risks and uncertainties may be amplified by the COVID-19 pandemic, which has caused significant economic uncertainty. The extent to which the COVID-19 pandemic impacts Veracyte's businesses, operations, and financial results, including the duration and magnitude of such effects, will depend on numerous factors, which are unpredictable, including, but not limited to, the duration and spread of the outbreak, its severity, the actions to contain the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume. These forward-looking statements speak only as of the date hereof and, except as required by law, 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.

Veracyte, Afirma, Percepta, Envisia, Prosigna, "Know by Design" and the Veracyte, Afirma, Percepta, Envisia and Prosigna logos are registered trademarks of Veracyte in the U.S. and selected countries.

Paper cited: Johnson, M.K., Wu, S., Pankratz, D.G. et al. Analytical validation of the Percepta genomic sequencing classifier; an RNA next generation sequencing assay for the assessment of Lung Cancer risk of suspicious pulmonary nodules. BMC Cancer 21, 400 (2021). https://doi.org/10.1186/s12885-021-08130-x

[1] Choi Y, Qu J, Wu S, Hao Y, Zhang J, Ning J, et al. Improving Lung Cancer risk stratification leveraging whole Transcriptome RNA sequencing and machine learning across multiple cohorts. BMC Med Genet. 2020;13(Suppl 10):151. https://doi.org/10.1186/s12920-020-00782-1

[2] World Health Organization

[3] American Lung Association

View source version on businesswire.com: https://www.businesswire.com/news/home/20210427005884/en/

Investor and Media Contact:
Tracy Morris
Vice President of Corporate Communications
& Investor Relations
tracy.morris@veracyte.com
650-380-4413

Source: Veracyte, Inc.