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Veracyte Announces Positive Clinical Utility Data for Percepta Classifier Published in CHEST

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 5, 2020-- Veracyte, Inc. (Nasdaq: VCYT) today announced the publication of new data demonstrating that the Percepta® classifier significantly reduces invasive procedures in lung cancer diagnosis by classifying nearly 40 percent of patients as “low risk” when bronchoscopy is inconclusive. The findings, from a large, prospective clinical study involving 35 centers, also suggest that these results are durable over a one-year follow-up and that the classifier results do not delay time to diagnosis among those patients with lung cancer. The study appears online in *CHEST*, the journal of the American College of Chest Physicians.

“Lung nodules are often difficult to diagnose when bronchoscopy results are indeterminate following initial work-up of the patient. As a result, physicians must determine whether to direct patients to further, invasive procedures or just monitor them, at the risk of missing a cancer and delaying necessary treatment,” said Giulia C. Kennedy, Ph.D., Veracyte’s chief scientific officer and chief medical officer. “The real-world findings published in *CHEST* show that use of the Percepta classifier significantly alters physicians’ pre-test clinical plans for an invasive procedure, enabling some patients to safely avoid the potential morbidity, mortality and cost associated with unnecessary, invasive procedures without delaying or shifting the stage of diagnosis among those who have lung cancer.”

The real-world registry study prospectively evaluated physicians’ management of lung nodules, as well as resulting clinical outcomes, at 35 academic and community-based U.S. medical centers. Researchers evaluated the impact of Percepta results on clinical decision-making for 213 patients with a low or intermediate pre-test risk of malignancy and a non-diagnostic bronchoscopy.

Comparing physicians’ pre-test to post-test plans for these patients, researchers observed a major shift following the Percepta classifier result. Among 67 patients for whom physicians had initially planned a subsequent invasive procedure, the Percepta test down-classified the risk of malignancy in 34.3 percent. Of these down-classified patients, physicians changed management plans for 73.9 percent - from an invasive procedure to surveillance - and 61 percent avoided a procedure for up to 12 months after initial evaluation.

In addition, researchers observed a larger absolute reduction in procedure rates among down-classified patients (61 percent vs. 52 percent, $p<0.01$), compared to those patients with unchanged risk.

Lastly, the time to diagnosis was not significantly delayed when comparing Percepta test down-classified patients to patients who were not down-classified ($p=0.58$), among all patients in the pre-test low and intermediate risk group who had confirmed lung cancers.

“The findings from this real-world multicenter study reinforce the large and growing body of evidence demonstrating that the Percepta classifier can reduce unnecessary invasive procedures for lung nodule patients when bronchoscopy findings are inconclusive,” said Bonnie Anderson, Veracyte’s chairman and chief executive officer. “These data are particularly important as physicians seek ways to limit their patients’ exposure to invasive procedures. We believe they will help support physician adoption of and payer reimbursement for the Percepta classifier.”

About the Percepta Classifier

The Percepta classifier is a novel genomic test that helps physicians determine individual patients’ lung cancer risk when results from bronchoscopy – a non-surgical procedure standardly used to assess lung nodules for cancer – are inconclusive. 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 classifier was developed using advanced genomic technology and machine learning, and is based on 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 covered by Medicare.

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 the ability of the Percepta classifier to reduce unnecessary invasive procedures for lung nodule patients. 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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