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New Data Published in PLOS ONE Validate the Clinical Performance of Veracyte's Percepta Genomic Sequencing Classifier in Lung Cancer Diagnosis

Findings from a large, multi-cohort study suggest the genomic test can improve care for lung nodule patients with inconclusive bronchoscopy results

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 13, 2022-- Veracyte, Inc. (Nasdaq: VCYT) announced that new data published today in PLOS ONE show that the company's Percepta Genomic Sequencing Classifier (GSC) is highly accurate in re-classifying lung cancer risk among patients with lung nodules whose bronchoscopy results are inconclusive. The authors also conclude that, based on findings from the large, multi-cohort study, use of the genomic test could enable a significant portion of patients to avoid unnecessary and invasive diagnostic procedures and offer the potential for earlier diagnosis.

"Quickly and accurately determining whether lung nodules identified through screening or incidentally are benign or malignant is critical to improve patient outcomes, but is often challenging. Physicians frequently use bronchoscopy to evaluate potentially cancerous lung nodules because it is less invasive than surgery, however, many times this procedure produces inconclusive results, leaving physicians and patients without clear guidance about what to do next," said Bill Bulman, M.D., Veracyte's medical director for lung cancer. "The findings from this study suggest that the Percepta GSC provides accurate, objective information that can help resolve this challenge."

Researchers evaluated the ability of the Percepta GSC to accurately classify risk of malignancy (ROM) in a blinded, independent set of 412 samples from lung nodule patients who were included in one of three, large study cohorts (AEGIS I/II and the Percepta Registry study). Each sample was classified pre-bronchoscopy as low, intermediate or high ROM and subsequently had a bronchoscopy result that was inconclusive.

Among patients with a pre-bronchoscopy intermediate ROM – which accounts for the largest group of lung nodules undergoing bronchoscopy – the Percepta GSC re-classified a total of 41% to either low or high risk. Patients in this cohort were re-classified to low risk with a 91% negative predictive value (NPV) or up-classified to high-risk with a 65% positive predictive value (PPV). Additionally, among pre-bronchoscopy low-risk nodules, the Percepta GSC down-classified 54.5% to very low risk with 100% sensitivity, indicating no false negatives, and a >99% NPV, and the test up-classified 27.3% of high-risk lesions to very-high risk with a specificity of 91.2% and 91.5% PPV. Across all pre-bronchoscopy risk groups, the Percepta GSC re-classified nearly 40% (39.1%) of patients into a different category of cancer risk.

The researchers also concluded that if the Percepta GSC results were used in this cohort of patients, 50% of those with low or intermediate pre-bronchoscopy ROM and benign lesions, as well as 29% of those with malignant lesions, who underwent additional invasive procedures could have avoided them.

"By accurately classifying lung nodules that have inconclusive bronchoscopy results, the Percepta GSC can help patients avoid unnecessary invasive procedures, and help ensure earlier diagnosis and more timely treatment for those at high risk of cancer," said Giulia C. Kennedy, Ph.D., Veracyte's global chief scientific officer and chief medical officer.

The Percepta GSC stratifies the risk of primary lung cancer across all pre-bronchoscopy risk groups to guide patient management when bronchoscopy is inconclusive. Veracyte developed the second-generation genomic test using RNA whole-transcriptome sequencing and machine learning, and by leveraging novel "field of injury" science through which genomic changes associated with lung cancer can be found in the airways of current or former smokers. The Percepta GSC is performed utilizing a sample collected from a brushing of the patient's main lung airway during a bronchoscopy. The test is covered by Medicare.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company that improves patient care by answering important clinical questions to inform diagnosis and treatment decisions. Our growing menu of advanced diagnostic tests help patients avoid risky, costly procedures and interventions, and reduce time to appropriate treatment. Our tests address eight of the 10 most prevalent cancers by incidence in the United States. In addition to making our tests available in the United States through our central laboratories, our exclusive license to a best-in-class diagnostics instrument positions us to deliver our tests to patients worldwide through laboratories that can perform them locally. 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 (GSC). Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "suggest," "may," "will" "prospective" and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. An example of a forward-looking statement includes, among others, that the Percepta GSC can help physicians accurately risk stratify lung nodules that receive inconclusive diagnostic results from bronchoscopy. 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 28, 2022, 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. 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.

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