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Veracyte Announces Next-Generation Percepta Genomic Sequencing Classifier Now Available to Physicians for Improved Lung Cancer Diagnosis

Genomic Test is Veracyte's First Commercial Product to Emerge Since Entering into Strategic Collaboration with Johnson & Johnson Innovation

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 26, 2019-- [Veracyte, Inc.](#) (Nasdaq: VCYT), a leading genomic diagnostics company, today announced that it has begun making its next-generation Percepta[®] Genomic Sequencing Classifier (GSC) available to physicians, providing them with expanded lung cancer risk information that can further guide next steps for patients with suspicious lung nodules, as compared to the original Percepta test. The RNA whole-transcriptome sequencing-based test is Veracyte's first commercial product to emerge since entering into the long-term strategic lung-cancer collaboration with Johnson & Johnson Innovation LLC*, which was announced in January 2019.

"Lung nodules are often challenging to diagnose using traditional tools, which can lead to unnecessary invasive procedures or to delayed treatment," said Giulia Kennedy, Ph.D., Veracyte's chief scientific and medical officer. "The ability to use genomic testing – such as the Percepta GSC – to determine which patients need intervention and those who may be safely monitored with routine imaging can help improve patient outcomes."

Veracyte's commercial introduction of the Percepta GSC follows the May 2019 presentation of clinical data showing that the genomic test down-classifies patients with suspicious lung nodules to "low risk" with a negative predictive value of 91 percent. This means these patients have a low likelihood of cancer and may therefore avoid unnecessary invasive procedures. The findings also show that the test up-classifies patients to high risk with a positive predictive value of 65 percent, suggesting that there is a higher likelihood these patients have cancer, which can help guide next intervention steps. The American College of Chest Physicians recommends lung nodule patients with a low risk of cancer undergo monitoring with CT imaging and that patients with a risk of 65 percent or greater undergo surgical treatment. The Percepta GSC study involved 412 lung-nodule patients whose results were inconclusive following bronchoscopy, a common nonsurgical procedure to assess lung nodules for cancer. The new study findings were shared during the American Thoracic Society 2019 International Conference.

The Percepta GSC utilizes machine learning and is built 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 performed on a sample from the patient's main lung airway, which is collected during a bronchoscopy. Veracyte estimates that approximately 360,000 bronchoscopies are currently performed each year to evaluate suspicious lung nodules for cancer and that up to 60 percent of these produce inconclusive results.

"We are excited to make the Percepta GSC available to physicians as an important tool that will help them further guide next steps for patients undergoing evaluation for suspicious lung nodules," said Bonnie Anderson, Veracyte's chairman and chief executive officer.

Veracyte is collaborating with the Lung Cancer Initiative at Johnson & Johnson to advance the development and commercialization of novel diagnostic tests to detect lung cancer at its earliest stages, when the disease is most treatable. The collaboration is accelerating two key lung cancer programs for Veracyte, including the commercialization of its Percepta classifier on the company's RNA whole-transcriptome sequencing platform well as the development of the first non-invasive nasal swab test for early lung cancer detection. Veracyte continues to expect to unveil early data for the nasal swab test later this year. Under terms of the agreement, Veracyte and the Lung Cancer Initiative at Johnson & Johnson will combine clinical study cohorts involving more than 5,000 patients with multiple years of clinical outcome data. Veracyte will contribute bronchial and nasal samples from its clinical trials, which are part of the company's extensive lung cancer-focused biorepository.

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.

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; the timing of the release of nasal swab data; our ability to achieve and maintain Medicare coverage for our tests, including the Envisia Genomic Classifier; the expected impacts of Veracyte's collaboration with Johnson & Johnson in developing interventions for lung cancer, on Veracyte's financial and operating results, on the timing of the commercialization of the Percepta classifier, and the size of Veracyte's addressable market. 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: our ability to achieve milestones under the collaboration agreement with Johnson & Johnson; 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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