



New Data Suggest Veracyte's Percepta Genomic Sequencing Classifier Can Help Accelerate Timely Treatment for Patients with Early-Stage Lung Cancer

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Findings demonstrate genomic test's expanded clinical utility in evaluating patients with lung nodules whose bronchoscopy results are inconclusive

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jan. 24, 2022-- Veracyte, Inc. (Nasdaq: VCYT) announced the publication of new data that suggest the company's Percepta Genomic Sequencing Classifier (GSC) can accelerate delivery of curative therapy for patients with high-risk lung nodules and inconclusive bronchoscopy results. The findings, from a prospective, randomized decision impact study [published in BMC Pulmonary Medicine](#), also show that the test can increase physician confidence in clinical decision-making and decrease unnecessary diagnostic procedures.

While many physicians use bronchoscopy to evaluate potentially cancerous lung nodules, results from the non-surgical procedure are often inconclusive, which can lead to diagnostic uncertainty and treatment delays. Veracyte developed the Percepta GSC to aid in the diagnosis of patients who have suspicious lung nodules and inconclusive bronchoscopy results. Clinical guidelines and data suggest patients with nodules identified as high-risk for lung cancer should be considered for immediate curative therapy (ablative therapy and/or surgery); however, studies have shown that physicians frequently opt for conservative management such as further surveillance or additional diagnostic procedures in these patients.

"Determining how to manage high-risk lung nodule patients who've had a non-diagnostic bronchoscopy is clinically challenging," said Sonali Sethi, M.D., FCCP, Interventional Pulmonology, Cleveland Clinic, and lead author of the paper. "The findings from our study suggest that, by accurately up-classifying patients' risk of malignancy from 'high' to 'very high,' this tool can help provide objective data that inform a more aggressive treatment approach in appropriate cases and increase physician confidence in their decision-making."

The Percepta GSC stratifies the risk of primary lung cancer to guide patient management when bronchoscopy is inconclusive. In the current, prospective, randomized decision-impact study, researchers evaluated whether a Percepta GSC result that up-classified a nodule's pre-bronchoscopy risk of malignancy (ROM) from "high" (>60%) to "very high" (>90%) led to an increase in the rate of referral for surgical or ablative therapy without additional intervening procedures and to an increase in physician confidence in patient management.

Using patient cases from the Percepta GSC validation cohort, researchers selected 37 cases that had a high ROM pre-bronchoscopy, a non-diagnostic bronchoscopy, and a Percepta GSC result that up-classified ROM from "high" to "very high." They presented these cases to 101 U.S.-based pulmonologists in three formats: a pre-post cohort where each case was presented without and then with a Percepta GSC result, and two independent cohorts where each case was presented either with or without a GSC result. Researchers then surveyed the physicians regarding subsequent patient management steps and confidence in their clinical decision.

The study found that Percepta GSC test results significantly increased the rate of recommendation for curative therapy (in alignment with current guideline recommendations) without additional, intervening procedures. Physicians who received the Percepta GSC result recommended surgical resection or ablative therapy more than twice as often as those who did not receive the test result (45% vs. 17%, respectively, $p < 0.001$). Among the pre-post cohort, the rate of recommendation increased from 17% to 56% ($p < 0.001$) following review of the Percepta GSC result. Additionally, pulmonologists' confidence in decision-making following a non-diagnostic bronchoscopy increased with the Percepta GSC up-classification. Prior to receiving the Percepta GSC result, 70% of physicians reported confidence level in their decision was at a 6 or 7 on a 7-point scale. This increased to 76% of physicians upon receipt of the Percepta GSC "very high" result, with a statistically significant increase at the highest possible level of 7 (from 21% to 31%; $p = 0.0017$).

"Both pulmonologists and patients are often confronted by a great deal of uncertainty when faced with a non-diagnostic bronchoscopy," said Giulia Kennedy, Veracyte's global chief scientific officer and chief medical officer. "These findings reinforce the clinical value and benefits of Veracyte's Percepta GSC, suggesting that the test could help improve outcomes for early-stage lung cancer patients by supporting recommended treatment approaches, reducing diagnostic delays and preventing unnecessary procedures."

About the Percepta Genomic Sequencing Classifier (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. 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

About Lung Cancer

Lung cancer kills more than 1.8 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 6 percent when it is found at a later stage.³ Lung nodules are typically the first sign of lung cancer, but most lung nodules are benign. Each year in the U.S., an estimated 1.6 million lung nodules are found incidentally on CT scans and, with recently expanded recommendations from the U.S. Preventive Services Task Force, an estimated 15 million Americans are eligible for annual lung cancer CT screening.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global 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 diagnostic tests leverages 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, colon cancer, and idiopathic pulmonary fibrosis are available to patients and its renal cancer and lymphoma subtyping tests are in development, the latter as a companion diagnostic. With Veracyte's exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its genomic 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 Classifier. 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. Examples of forward-looking statements include, among others, statements regarding Veracyte's belief that its Percepta Genomic Classifier can improve the diagnosis of lung cancer, and assist healthcare providers in making treatment decisions. 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. 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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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 Gen. 2020;13(Suppl 10):151. <https://doi.org/10.1186/s12920-020-00782-1>

² World Health Organization

³ American Lung Association

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