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Veracyte Announces Publication of Data Demonstrating Potential for Non-Invasive Nasal Test to Improve Lung Cancer Diagnosis

Findings reinforce validity of 'field-of-injury' innovation that led to development and launch of Percepta® Bronchial Genomic Classifier

SOUTH SAN FRANCISCO, Calif., Feb. 27, 2017 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a genomic diagnostics company focused on reducing unnecessary surgeries and healthcare costs by resolving diagnostic uncertainty, announced that data published for the first time today in the *Journal of the National Cancer Institute (JNCI)* demonstrate the potential for a non-invasive nasal test to help improve the safety and accuracy of lung cancer detection among current and former smokers.

"The data published today provide compelling evidence that molecular biomarkers used to determine lung cancer risk in cells from the bronchial airway could provide similar information as cells obtained from a simple nasal swab. This discovery could offer a method to further reduce the uncertainty, risk and cost associated with the early detection of lung cancer," said Avrum Spira, M.D., M.Sc., professor of medicine at Boston University School of Medicine and corresponding author on the *JNCI* paper. "This need is especially urgent given the growing number of lung-cancer screening programs in the United States."

The new findings build on research previously conducted by Dr. Spira and a team from Boston University, which demonstrated that cells in the central bronchial airways of the lung exhibit measurable cancer-associated gene-expression changes due to smoking. These collective genomic alterations comprise a "field of injury," which serves as a biomarker distinguishing ever-smokers with lung cancer from those with benign lung disease, independent of clinical risk factors. The field-of-injury innovation is the foundation for Veracyte's Percepta Bronchial Genomic Classifier, which evaluates patient samples obtained by bronchoscopy to improve lung cancer screening and diagnosis.

In the current study, Boston University researchers sought to expand upon the earlier findings, evaluating whether smoking produces similar field-of-injury genomic alterations in the cells lining human nasal passages. The investigators prospectively collected nasal epithelial cells from 505 current and former smokers undergoing diagnostic evaluation for pulmonary lesions in two, prospective multi-center clinical studies (AEGIS-1 and AEGIS-2).

After one year of follow up, researchers identified differentially expressed genes in the nasal epithelium of AEGIS-1 patients who were diagnosed with lung cancer vs. those with benign disease ($p < 0.001$). They also confirmed significant consistency between the field-of-injury alterations found in paired samples of cells from the lower and upper airways (i.e., bronchial and nasal epithelial cells).

Finally, the researchers determined that a non-invasive nasal classifier comprising 30 of the most differentially expressed genes significantly enhanced the ability of a risk model based only on clinical factors (e.g., age, smoking status) to predict lung-cancer status.

"The landmark findings published today reinforce the validity and clinical importance of the field-of-injury innovation underlying our Percepta Bronchial Genomic Classifier, which has already demonstrated the ability to reduce ambiguity in lung cancer diagnosis and thereby reduce the unnecessary, invasive and costly procedures that can result," said Bonnie Anderson, chairman of the board, president and chief executive officer of Veracyte. "We look forward to exploring the potential for a non-invasive genomic nasal classifier that can expand upon the meaningful benefits provided by the Percepta test."

The Veracyte Percepta classifier detects field of injury-associated genomic changes in cells collected by bronchoscopy, a minimally invasive procedure, to determine the likelihood that a lung nodule or lesion detected by CT scan is cancerous. In the AEGIS-1 and -2 studies, Percepta combined with bronchoscopy demonstrated a cancer-detection sensitivity of 97 percent as compared to 75 percent sensitivity for bronchoscopy alone. The test has demonstrated a high degree of accuracy (negative predictive value of 91 percent) in identifying patients at low (< 10 percent) risk of cancer, allowing these patients to be monitored noninvasively with imaging and avoid further unnecessary, risky and costly invasive procedures.

Veracyte acquired rights to the Percepta classifier and its underlying technology and intellectual property through its 2014

acquisition of Allegro Diagnostics.

About Veracyte
Veracyte (NASDAQ: VCYT) is a leading genomic diagnostics company that is fundamentally improving patient care by resolving diagnostic uncertainty with evidence that is trustworthy and actionable. The company's products uniquely combine genomic technology, clinical science and machine learning to provide answers that give physicians and patients a clear path forward without risky, costly surgery that is often unnecessary. Since its founding in 2008, Veracyte has commercialized three genomic tests, which are transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis and collectively target a $2 billion market opportunity. 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 Statement
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, our ability to successfully scale the company and our belief that we are well positioned for profitable growth. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Forward-looking statements involve risks and uncertainties, which could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the applicability of clinical results to actual outcomes; laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; the size of the market opportunity for our products; our ability to successfully achieve 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; our products' ability to become the standard of care; the occurrence and outcomes of clinical studies; the timing and publication of clinical study results; and other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.