October 25, 2016

Veracyte Announces Launch of Envisia™ Genomic Classifier for Improved Diagnosis of Idiopathic Pulmonary Fibrosis at CHEST Annual Meeting 2016

-- Company's third commercial test uses machine learning and deep RNA sequencing to identify genomic patterns signifying the presence of IPF --
-- Data demonstrate clinical validity of first-of-its-kind genomic classifier --

SOUTH SAN FRANCISCO, Calif., Oct. 25, 2016 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a genomic diagnostics company that reduces unnecessary surgeries and healthcare costs by resolving diagnostic uncertainty, announced the launch of the Envisia Genomic Classifier at the CHEST Annual Meeting 2016 in Los Angeles. Envisia is expected to be the first commercially available test to help patients with suspected idiopathic pulmonary fibrosis (IPF) secure accurate diagnoses more quickly than the currently available process and without the need for invasive surgery.

Each year in the United States and Europe, up to 200,000 patients are suspected of having an interstitial lung disease (ILD), including IPF, which is among the most common and most deadly of these lung-scarring diseases. IPF is notoriously difficult to diagnose, often leading to treatment delays, repeated misdiagnoses, patient distress and added healthcare expense. Veracyte estimates that by helping to improve care for these patients, the company is targeting a $500 million market in the United States and Europe.

The Envisia classifier uses machine learning coupled with powerful, deep RNA sequencing to detect the presence or absence of usual interstitial pneumonia (UIP), a classic diagnostic pattern that is essential for the diagnosis of IPF. Physicians routinely use high-resolution CT imaging (HRCT) to identify UIP, but this approach frequently provides inconclusive results, leading many patients to undergo surgery to secure a more definitive diagnosis using surgical histopathology. Veracyte scientists trained the Envisia classifier to differentiate UIP from non-UIP on patient samples obtained through less-invasive outpatient bronchoscopy.

During a private event with leading pulmonologists and other IPF-treating physicians at CHEST 2016, Giulia C. Kennedy, Ph.D., chief scientific officer of Veracyte, presented data demonstrating the clinical validity of the Envisia classifier. The test was trained on over 350 samples obtained through bronchoscopy from 90 patients participating in the ongoing, prospective 30-site BRAVE study. The researchers then evaluated the clinical validity of the locked 190-gene classifier using an independent set of samples from 49 BRAVE study participants, confirming that Envisia detects UIP vs. non-UIP with high specificity (88 percent). The classifier reported sensitivity of 67 percent, meaning it would be expected to identify nearly two-thirds of UIP cases. These results show high concordance with the presence or absence of a UIP pattern reported on surgical histopathology review by a centralized panel of pathologists with expertise in ILD.

"The availability of a clinically validated genomic classifier for patients with suspected IPF will be a significant step forward in ensuring an accurate and timely diagnosis," said Ganesh Raghu, M.D., professor of medicine in the Division of Pulmonary and Critical Care Medicine and director of the Center for Interstitial Lung Disease at the University of Washington. "In the current diagnostic pathway, an accurate diagnosis may require a surgical lung biopsy to confirm the presence of UIP. This is an invasive, costly and potentially risky procedure."

"Patients with suspected ILD, including IPF, endure a significant delay in diagnosis, frequent misdiagnosis and often require invasive procedures to get definitive answers," said Gregory Cosgrove, M.D., associate professor of medicine, National Jewish Health and CMO of the Pulmonary Fibrosis Foundation (PFF). "Better tools are needed to reduce the clinical impact, anxiety and cost involved in an IPF diagnosis. Based on the clinical validity data shared here this week, the Envisia classifier could help to fill this compelling, unmet need."

Veracyte will begin making the Envisia Genomic Classifier available to a limited number of institutions in December, as the company builds the clinical evidence it believes will be necessary to support Medicare reimbursement. This strategic roll out follows the successful commercialization and reimbursement approach that the company used with its tests in thyroid cancer (Afirma® Gene Expression Classifier) and lung cancer (Percepta® Bronchial Genomic Classifier).

"Veracyte now has three commercial products in major disease markets that we estimate to be more than $2 billion," said Bonnie Anderson, president and chief executive officer of Veracyte. "The Envisia classifier is a further demonstration of our commitment to significantly improve patient care by reducing diagnostic uncertainty. We believe it is the first clinically available test to combine deep RNA sequencing with machine learning algorithms, and it serves as an excellent demonstration of our ability to push the limits of genomic science to create novel, valuable diagnostic tools that change clinical care."

About Veracyte

Veracyte (NASDAQ: VCYT) is pioneering the field of molecular cytology, offering genomic solutions that resolve diagnostic ambiguity and enable physicians to make more informed treatment decisions at an early stage in patient care. By improving preoperative diagnostic accuracy, the company aims to help patients avoid unnecessary invasive procedures while reducing healthcare costs. Veracyte's Afirma® Thyroid FNA Analysis centers on the proprietary Afirma Gene Expression Classifier (GEC) and is becoming a new standard of care in thyroid nodule assessment. The Afirma test is recommended in leading practice guidelines and is covered for 185 million lives in the United States, including through Medicare and many commercial insurance plans. Veracyte is expanding its molecular cytology franchise to other clinical areas, beginning with difficult-to-diagnose lung diseases. In 2015, the company launched the Percepta® Bronchial Genomic Classifier, a test to evaluate patients with lung nodules that are suspicious for cancer, which has already received draft Medicare coverage. In October 2016, Veracyte launched its second pulmonology product, the Envisia™ Genomic Classifier, to improve diagnosis of interstitial lung diseases, including idiopathic pulmonary fibrosis. For more information, please visit www.veracyte.com.

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 we make regarding the benefits of Envisia to patients, physicians and payers, our belief that the use of the Percepta classifier helps reduce surgery and other costly procedures, our belief that the availability of the company's test is an advance toward ensuring more accurate and timely diagnoses, the limitations of current diagnostic procedures, the company's belief that it will be able to build the clinical evidence necessary to support Medicare reimbursement for its test, the company's belief that Envisia is the first clinically available test of its kind, our belief that the test demonstrates the company's ability to push the limits of genomic science to create novel tools that change clinical care, the applicability of clinical results to actual outcomes, and the company's beliefs regarding the potential markets for Envisia and the company's other products . 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 ability of Envisia to change physicians' practices; 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 Envisia; 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; 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 June 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.