May 27, 2016

Veracyte Announces New Data that Advance Understanding of the Role of Gene Alterations In Thyroid Cancer Diagnosis

-- Findings presented at the American Association of Clinical Endocrinologists (AACE) Meeting --

SOUTH SAN FRANCISCO, Calif., May 27, 2016 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today announced findings from two studies demonstrating the challenge of using large gene-mutation panels to help physicians determine next steps for patients whose thyroid nodules are not clearly benign or malignant following routine cytopathology evaluation. Company researchers also unveiled a new study designed to identify RNA-based gene alteration and other data that may be useful in guiding physician decision-making for thyroid nodule patients. The studies are being presented at the American Association of Clinical Endocrinologists (AACE) 25th Annual Scientific & Clinical Congress, taking place May 25-29, 2016, in Orlando, Fla.

More than 525,000 Americans are evaluated for potentially cancerous thyroid nodules each year. While most nodules are benign, up to 30 percent are deemed inconclusive based on microscope-based review. Traditionally, many of these patients have been directed to thyroid surgery for more definitive results, only for most (70-80 percent) to learn after the invasive, costly procedure that their nodules were benign.

"As gene alterations and fusions are linked increasingly to thyroid cancer in the literature, there is growing interest among clinicians regarding how this genomic information can be used to enhance thyroid cancer diagnosis," said Giulia C. Kennedy, Ph.D., chief scientific officer of Veracyte. "Findings from two studies presented at the AACE meeting, however, suggest that gene variant and fusion panels on their own have limited ability to help rule in or rule out cancer in patients with indeterminate thyroid nodules. These results are consistent with previous findings and underscore the need to clarify the role that gene alterations may potentially play in guiding the care of patients being evaluated for potential thyroid cancer."

In the first study, researchers conducted a meta-review of the relevant body of literature to determine the value of RAS mutations - which have been linked to thyroid cancer - in identifying malignancy in indeterminate thyroid nodules. In a review of 17 studies involving 2,035 cytologically indeterminate nodules, RAS mutations had a sensitivity of 30 percent, suggesting that 70 percent of cancers would be missed if RAS mutations were used to rule out cancer. In a review of 19 studies involving 2,099 thyroid nodules, RAS mutations were found in 13 percent of benign nodules, suggesting that their use to identify malignancy could lead to unnecessary treatment of many patients who do not have cancer.

In a second study, Veracyte scientists used DNA sequencing to evaluate the ability of three large gene-mutation panels to rule in or rule out cancer in 82 thyroid fine needle aspiration (FNA) samples and 38 thyroid tissue samples. The researchers found that a panel targeting 229 alterations in 14 genes had a sensitivity of only 55 percent for detecting cancer (i.e., it missed cancer 45 percent of the time). A custom panel of 854 alterations in 357 genes derived from the literature and The Cancer Genome Atlas had a sensitivity of just 67 percent. Using a 358-gene panel (The Jackson Laboratory Cancer Treatment Profile), the researchers found that the sensitivity increased to 90 percent, but was accompanied by a low (11 percent) specificity (i.e., it elicited many false positives).

Veracyte and external researchers also presented the design of a new study to advance the understanding of genomic alterations and transcriptional expression in thyroid nodule patients with indeterminate cytopathology. Through the Evaluation of Thyroid FNA Genomic Signatures (ENHANCE) trial, Veracyte has established a comprehensively annotated bio-repository of FNA samples that are tagged with genomic and histopathology data, as well as clinical and radiological information when possible, to determine which features signal cancer - and in what relation to each other - and which do not. As of December 2015, 39 academic and community study sites have opened across the United States and 650 patients have enrolled in the study.

"We look forward to the ENHANCE study helping us better understand the role of genomic alterations and other factors in thyroid cancer and to determine how this information could potentially be used with our Afirma® Gene Expression Classifier (GEC) to further guide care for thyroid nodule patients," said Dr. Kennedy.

About Afirma
Veracyte's Afirma Thyroid FNA Analysis is a comprehensive solution for improved thyroid nodule assessment. It centers on the Afirma GEC, a 142-gene molecular test that identifies benign thyroid nodules among those deemed indeterminate by cytopathology, enabling these patients to potentially avoid an unnecessary surgery. An additional 25 genes are used to differentiate uncommon neoplasm subtypes. The company's Afirma Malignancy Classifiers - comprising tests for medullary thyroid cancer and BRAF gene mutation status - are designed to inform surgical strategy for those patients headed to surgery based on their cytopathology or Afirma GEC results.

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 180 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 April 2015, the company launched the Percepta® Bronchial Genomic Classifier, a test to evaluate patients with lung nodules that are suspicious for cancer. In the fourth quarter of 2016, Veracyte plans to launch its second pulmonology product, the Envisia™ 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 our beliefs regarding the drivers of adoption of Afirma, our expectations with respect to the success of our entry into the pulmonology market, our expectations regarding full-year 2016 guidance and forecast for annual GEC test volume, and the value and potential of our technology and research and development pipeline. 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: our limited operating history and history of losses; our ability to increase usage of and reimbursement for Afirma and to obtain reimbursement for any future products we may develop or sell; our ability to continue our momentum and growth; our dependence on a few payers for a significant portion of our revenue; the complexity, time and expense associated with billing and collecting from payers for our tests; laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; our dependence on strategic relationships and our ability to successfully convert new accounts resulting from such relationships; our ability to develop and commercialize new products and the timing of commercialization; our ability to successfully achieve adoption of and reimbursement for our Percepta Bronchial Genomic Classifier; our ability to achieve sales penetration in complex commercial accounts; the occurrence and outcome of clinical studies; the timing and publication of study results; the applicability of clinical results to actual outcomes; our inclusion in clinical practice guidelines; the continued application of clinical guidelines to our products; our ability to compete; our ability to expand into international markets and achieve adoption of our tests in such markets; our ability to obtain capital when needed; 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 March 31, 2016. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.