March 6, 2015

Veracyte Announces New Data that Inform Optimal Use of Molecular Testing in Preoperative Thyroid Nodule Assessment

- Data Presented This Week at ENDO 2015 Annual Meeting -

SOUTH SAN FRANCISCO, Calif., March 6, 2015 /PRNewswire/ -- Veracyte, Inc. (Nasdaq: VCYT) today announced new data demonstrating that diagnostic tests that use increasing numbers of cancer-associated gene mutations to evaluate thyroid nodules can dramatically reduce the specificity of test results, leading to an increase in "false positives," in which benign nodules are erroneously diagnosed as cancerous. In addition, these new data show that some mutational panels actually miss half of the malignancies leading to "false negatives." The data were presented this week at ENDO 2015, the 97th annual meeting of the Endocrine Society, in San Diego, Calif., and reinforce the role of the Afirma Gene Expression Classifier (GEC) to rule out cancer in thyroid nodules with high negative predictive value and suggest exercising caution in interpreting mutational data in these nodules.

Researchers evaluated fine needle aspiration (FNA) and other samples from a total of 239 thyroid nodules using next-generation sequencing (NGS) technology that measured a progressively larger set of gene variants associated with thyroid cancer. Results demonstrate a dramatic, inverse relationship between the sensitivity and specificity of these tests: While sensitivity to detect malignancy improved in all groups with the increasing number of variants evaluated, specificity fell dramatically. In FNA biopsy samples, for example, the smallest panel resulted in a sensitivity of 53 percent and a specificity of 93 percent. The largest panel generated a sensitivity of 100 percent and a specificity of 0.4 percent. Overall, the two largest genomic panels wrongly called as cancerous 87-90 percent of thyroid nodules that were benign based on microscopic tissue evaluation.

"False positive" test results can lead to unnecessary surgical removal of the thyroid gland, as well as significant anxiety for patients and increased costs to the healthcare system. "False negative" test results lead to patients with malignancies not getting the surgery they need.

"As the scientific community gains more experience with NGS, we will continue to identify greater numbers of thyroid cancer-associated genomic aberrations," said Giulia C. Kennedy, PhD, Veracyte's chief scientific officer and lead researcher for the study. "But the sensitivity gained by applying increasingly larger numbers of variants to preoperatively evaluate thyroid nodules may come at the cost of specificity, and create the risk of a cancer diagnosis in truly benign nodules. Conversely, our data also show that some of the commonly used panels are not sensitive enough to detect all the cancers, leading to a conundrum of how best to manage the patient. Our results suggest that further study is needed to elucidate the clinical utility of such mutation panels in helping physicians make surgical decisions on patients with indeterminate thyroid nodules."

Results from a second study, in collaboration with and presented by Memorial Sloan Kettering Cancer Center researchers at ENDO 2015 this week, demonstrate the potential for novel molecular classifiers developed by Veracyte scientists to improve preoperative prediction of cancer recurrence in malignant thyroid nodules.

In this study, researchers utilized FNA material from 79 thyroid nodule samples from patients who were post-surgically diagnosed with papillary thyroid carcinoma (PTC). Each sample was categorized as either "low risk" or "intermediate/high risk" of recurrence using established, post-operative recurrence-risk stratification guidelines (2009 American Thyroid Association). Employing molecular classifiers built using 320 genes, researchers were able to stratify recurrence risk for each of the 79 FNA samples with relatively high levels of accuracy. The highest-performing classifier correctly identified 79 percent of ATA "low-risk" tumors and 82 percent of ATA "intermediate/high risk" tumors.

"This study presents encouraging data that new molecular classifiers may provide physicians with additional, important information about thyroid nodules in advance of surgery," said R. Michael Tuttle, M.D., endocrinologist at Memorial Sloan Kettering Cancer Center. "By stratifying recurrence risk preoperatively among patients with cancer who are headed to surgery, physicians would be able to better guide the extent of surgery and radioactive iodine treatment, which could lead to improved outcomes and reduced costs and morbidity."

About Afirma®

Veracyte's Afirma Thyroid FNA Analysis is a comprehensive solution for improved thyroid nodule assessment. It centers on the Afirma Gene Expression Classifier (GEC), a molecular test that identifies benign thyroid nodules among those deemed indeterminate by cytopathology, enabling these patients to potentially avoid an unnecessary surgery. 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 and/or Afirma GEC results.

About Veracyte
Veracyte (Nasdaq: VCYT) is pioneering the field of molecular cytology, focusing on 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 first commercial solution, the Afirma® Thyroid FNA Analysis, centers on the proprietary Afirma Gene Expression Classifier (GEC) to resolve ambiguity in diagnosis and is becoming a new standard of care in thyroid nodule assessment, since its launch in 2011. As of September 30, 2014, Veracyte estimates its Afirma solution has helped approximately 10,000 patients with thyroid nodules avoid unnecessary surgery, reducing healthcare costs by millions of dollars. Afirma is recommended in leading practice guidelines and is covered for more than 140 million lives in the United States, including through Medicare and most commercial insurance plans. Veracyte intends to expand its molecular cytology franchise to other clinical areas, beginning with difficult-to-diagnose lung diseases. The company expects to launch the Percepta™ Bronchial Genomic Classifier, a test to resolve preoperative ambiguity in lung nodules that are suspicious for cancer, in 2015. Veracyte is also developing a second product in pulmonology, targeting 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 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 the Afirma Gene Expression Classifier, the Afirma Malignancy Classifiers and 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 test; 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 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; 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 September 30, 2014. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.

Media:
Tracy Morris
650-380-4413
tracy.morris@veracyte.com

Investors:
Ami Bavishi
Burns McClellan, Inc.
212-213-0006
abavishi@burnsmc.com

SOURCE Veracyte