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Veracyte Announces Publication of Study Reinforcing the Clinical Utility of the Afirma® Gene Expression Classifier in Thyroid Cancer Diagnosis

SOUTH SAN FRANCISCO, Calif., Feb. 19, 2016 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, announced that an independent clinical utility study reinforcing the ability of the Afirma Gene Expression Classifier (GEC) to significantly reduce unnecessary surgeries in thyroid cancer diagnosis was published in the February issue of *Cancer Cytopathology.*

Researchers from the David Geffen School of Medicine at the University of California at Los Angeles evaluated all thyroid nodule fine needle aspirations (FNAs) performed during a 20-month period following introduction of the Afirma GEC at the institution to determine its impact on clinical practice. The genomic test is used when patients' thyroid nodule FNA results are deemed inconclusive by traditional cytopathology and helps identify patients whose thyroid nodules are actually benign - and who can thus safely avoid unnecessary diagnostic surgery.

Among 174 patients with indeterminate cytopathology results during the study period, the Afirma GEC identified 80 as benign (46 percent) and, of the five patients with benign Afirma GEC results who underwent surgery, all five nodules proved to be benign based on the histopathology findings. Additionally, in the two primary categories of indeterminate results ("AUS-FLUS" and "SFN-FN"), use of the Afirma GEC reduced overall surgeries - among all patients tested, regardless of test results - from 49 percent to 33 percent and from 63 percent to 50 percent, respectively. Similarly, use of the genomic test increased the overall rate of cancer found when surgery was performed, from 35 percent to 47 percent for AUS-FLUS and from 33 percent to 50 percent for SFN-FN cases, respectively.

In the paper, the authors conclude, "Finally, the question remains whether Afirma GEC testing has refined the indeterminate thyroid category in cytology. The answer in our opinion is a qualified 'yes' because it excludes approximately 40 percent to 50 percent of the benign cases from surgery and results in a relatively higher percentage of malignant lesions in the surgical outcome."

"These findings further reinforce the role of the Afirma GEC as a new standard of care in thyroid cancer diagnosis, where it has helped tens of thousands of patients across the country avoid unnecessary thyroid surgery, and the morbidity and anxiety that can accompany such surgery, while also reducing healthcare costs," said Bonnie Anderson, president and chief executive officer of Veracyte.

According to the American Cancer Society, thyroid cancer is the fastest-increasing cancer in the United States, with more than 64,000 new cases expected in 2016. Among the approximately 525,000 fine-needle aspirations performed on patients with thyroid nodules each year in the United States, 15-30 percent of the results are inconclusive in ruling out cancer, and most physicians have traditionally recommended thyroid surgery for final diagnosis. Following surgery, however, 70-80 percent of these patients' nodules are diagnosed as benign.

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, 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 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 nearly 175 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. Veracyte is 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 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 2015 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 September 30, 2015. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.