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New American Thyroid Association Guidelines Include Recommendation for Veracyte's Afirma® Gene Expression Classifier to Rule Out Cancer in Indeterminate Thyroid Nodules

SOUTH SAN FRANCISCO, Calif., Oct. 15, 2015 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today announced that new guidelines from the American Thyroid Association (ATA) include a recommendation that the Afirma Gene Expression Classifier (GEC) may be used in lieu of diagnostic surgery to rule out cancer in patients whose thyroid nodules are deemed indeterminate following traditional cytopathology. The Afirma GEC is the only molecular test with a high enough sensitivity and negative predictive value, demonstrated in prospective, multicenter, blinded studies, to be recommended as an option for such use.

"We commend the ATA and its guideline committee for their extensive work and focus on evidence-based recommendations," said Bonnie Anderson, Veracyte's president and chief executive officer. "We are especially pleased that the guidelines highlight the data supporting the Afirma GEC, including the rigorous clinical validation study published in *The New England Journal of Medicine*, which demonstrated its sensitivity of 90 percent and negative predictive value of greater than 94 percent.

"We continue to build the strong evidence supporting the use and reimbursement of the Afirma GEC. Ten clinical utility studies now include two recently published long-term clinical outcome studies, as well as two additional clinical-utility studies to be presented next week at the International Thyroid Congress. Importantly, the Afirma GEC is now covered for approximately 150 million Americans through their health insurance plans."

The Afirma GEC-related recommendations that appear in the new ATA guidelines include the two major categories of indeterminate thyroid nodules based on cytopathology: atypia of undetermined significance/follicular lesion of undetermined significance (AUS/FLUS) and follicular neoplasm/suspicious for follicular neoplasm (FN/SFN). The guidelines appear online in the journal *Thyroid*.

"Historically, patients at our hospital whose thyroid nodules were indeterminate on two consecutive biopsies were recommended for surgical excision for definitive diagnosis," said Peter M. Sadow, M.D., Ph.D., associate director, head and neck pathology, at Massachusetts General Hospital. "Given the high sensitivity and negative predictive value associated with the Afirma GEC, physicians can confidently recommend non-surgical follow-up for patients whose nodules are classified as benign by this genomic test. This is an important tool to be able to offer to patients."

The Afirma GEC, introduced in 2011, is 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. The test is already recommended in leading guidelines, including those of the National Comprehensive Cancer Network® and UpToDate.® 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.

According to the American Cancer Society, thyroid cancer is the fastest-increasing cancer in the United States, with more than 62,000 new cases expected in 2015. 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 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 approximately 150 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 t 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 June 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.

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* An additional 25 genes are incorporated into the test to distinguish rare neoplasms.