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Veracyte Announces Publication of Long-Term Clinical Utility Study for the Afirma® Gene Expression Classifier

SOUTH SAN FRANCISCO, Calif., Jan. 22, 2016 /PRNewswire/ --Â Veracyte, Inc. (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, announced that data demonstrating the ability of the Afirma Gene Expression Classifier (GEC) to reduce thyroid surgeries during three years of follow-up were published online in *Endocrine Practice*, the journal of the American Association of Clinical Endocrinologists (AACE).

The study provides the longest-term follow-up information published to date for the genomic test, which is used to identify patients whose thyroid nodules are benign following inconclusive fine needle aspiration (FNA) biopsy results, so that they can potentially avoid unnecessary diagnostic surgery and be monitored with ultrasound imaging instead.

Researchers assessed surgery rates for patients with benign Afirma GEC results who were tested at 16 community-based practices across the United States and were followed for 36 months. They found that 82.7 percent of patients (81 out of 98) with a benign Afirma GEC result avoided surgery during the follow-up period, with the majority (88 percent) of any surgeries occurring within the first two years. In comparison, the historical rate of surgery avoidance is just 26 percent among thyroid nodule patients with indeterminate cytopathology results.

"Our data suggest that use of the Afirma GEC can significantly reduce surgery rates among patients with indeterminate thyroid nodules, over an extended period of time, compared to how these patients were historically managed," said Jennifer A. Sipos, M.D., associate professor of medicine at The Ohio State University and lead author of the study. "This study is noteworthy because it provides the longest-term data to date regarding the durability of a benign Afirma GEC result."

The study findings were also presented recently at the 15th International Thyroid Congress (ITC) and 85th Annual Meeting of the American Thyroid Association.

"This study further reinforces the significant value that the Afirma GEC is delivering to patients, physicians and the healthcare system by helping patients avoid unnecessary, invasive and costly thyroid surgeries just to get a diagnosis," said Bonnie Anderson, Veracyte's president and chief executive officer. "The Afirma GEC's clinical utility is now demonstrated in more than a dozen studies published in peer-reviewed journals. We believe that this rigorous clinical evidence, along with the test's inclusion in all of the recently updated, thyroid-focused medical guidelines, will support its continued adoption and reimbursement."

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 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.Â

About Veracyte
VeracyteÂ (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.Â Veracyte'sÂ 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 inÂ the United States, including throughÂ Medicare and many commercial insurance plans.Â VeracyteÂ is expanding its molecular cytology franchise to other clinical areas, beginning with difficult-to-diagnose lung diseases. InÂ April 2015, the company launched the Percepta™ Bronchial Genomic Classifier, a test to evaluate patients with lung nodules that are suspicious for cancer.Â VeracyteÂ is developing a second product in pulmonology, targeting interstitial lung diseases, including idiopathic pulmonary fibrosis. For more information, please visitÂ 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;Â 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 theÂ Food and Drug AdministrationÂ or other regulatory bodies;Â 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 theÂ Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter endedÂ September 30, 2015. These forward-looking statements speak only as of the date hereof andÂ VeracyteÂ specifically disclaims any obligation to update these forward-looking statements.

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