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Veracyte Announces Publication of New Long-Term Outcome Study that Reinforces the Clinical Utility of the Afirma® Gene Expression Classifier

SOUTH SAN FRANCISCO, Calif., Sept. 14, 2015 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today announced the publication of new long-term outcome data supporting the use of the Afirma Gene Expression Classifier (GEC) to identify patients whose thyroid nodules are noncancerous - and can thus safely avoid unnecessary surgery - when their fine needle aspiration (FNA) biopsy results are inconclusive. The study, led by researchers at Brigham and Women's Hospital, appears online in *The Journal of Clinical Endocrinology & Metabolism*.

"Our findings show that thyroid nodules classified as benign by the Afirma GEC have similar growth during follow-up as nodules that are benign by cytopathology, which suggests comparable clinical behavior," said Trevor E. Angell, M.D., endocrinologist at Brigham and Women's Hospital and lead author of the new study. "These data suggest that physicians can confidently monitor patients with benign GEC results, just as they would with patients whose cytopathology results are benign."

The researchers evaluated 90 patients whose thyroid nodule FNAs were deemed benign by the Afirma GEC (following indeterminate cytopathology) between 2010 and 2014. Using ultrasound data available for 58 nodules in 56 of the patients, they compared rates of significant growth - an indicator of potential cancer - over a median of 13 months (range of 4-40 months) to those of 1224 thyroid nodules with benign cytopathology results. The latter were from 873 patients who underwent FNA procedures over a ten-year period prior to introduction of the Afirma GEC and who were followed with ultrasound for a similar period of time.

They found that Afirma-benign nodules showed similar growth as the cytopathology-benign cases using either of two criteria: greater than or equal to 20 percent in two dimensions (8.6 percent vs. 8.3 percent) or greater than or equal to 50 percent in volume (17.2 percent vs. 13.8 percent). Patients in the Afirma-benign group were more likely to undergo surgery (13.8 percent vs. 0.9 percent), but cancer was only found in one patient.

The authors note that they report on change in Afirma-benign nodules during a clinically relevant monitoring period, as cytologically benign thyroid nodules are typically followed with ultrasound at 6-18 months. Additionally, most of the patients studied remain in the care of Brigham and Women's Hospital, with up to four years of follow-up since their initial Afirma-benign result.

"These findings add to the growing body of rigorous clinical evidence that underscores the clinical utility of the Afirma GEC in helping patients with thyroid nodules avoid unnecessary surgery, while reducing healthcare costs," said Bonnie H. Anderson, Veracyte's president and chief executive officer. "We believe that, with its demonstrated value to patients, physicians and payers, the Afirma GEC is becoming the new standard of care in thyroid cancer diagnosis." Since its introduction the Afirma GEC has been performed on nearly 40,000 patients.

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 (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. 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, 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.