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Veracyte Presents Data Demonstrating Potential to Enhance Afirma® Gene Expression Classifier Using an RNA Sequencing Platform

Seven Afirma GEC Studies Presented at the 86th Annual Meeting of the American Thyroid Association

SOUTH SAN FRANCISCO, Calif., Sept. 23, 2016 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT) today announced new data suggesting the potential to enhance the performance of the Afirma Gene Expression Classifier in thyroid cancer diagnosis by combining the test's proven RNA expression-based capabilities with gene variant and fusion information - all on a single, robust RNA sequencing platform. Such enhancements could help to further reduce the number of patients who undergo unnecessary surgery when their thyroid nodules are not clearly benign or cancerous (i.e., indeterminate) following routine cytopathology evaluation.

Veracyte scientists presented the findings today in a poster session at the 86th Annual Meeting of the American Thyroid Association, being held in Denver through September 25. Six additional posters are being presented at the ATA meeting by external researchers and underscore the Afirma GEC's role as a new standard of care in thyroid cancer diagnosis.

In the Veracyte study, company researchers used RNA from 88 thyroid nodule patient samples for which a surgical pathology diagnosis was known to train (with 58 samples) and test (with 30 samples) an enhanced version of the Afirma GEC. Using advanced machine-learning techniques, Veracyte leveraged an RNA sequencing platform to combine the genomic test's RNA gene expression-based algorithm with gene variant and fusion information. The result was an enriched classifier that yielded an overall area under curve (AUC) of 0.88, with a sensitivity of 93 percent and a specificity of 80 percent.

"Numerous efforts have been made to diagnose indeterminate thyroid nodules using cancer-associated DNA mutation and fusion information. However, research is increasingly showing the limitations of this approach in clinical practice because such gene alterations are found in both cancerous and benign patients," said Giulia C. Kennedy, Ph.D., Veracyte's chief scientific officer, who presented the new data. "We believe that our study is the first to show that, using a powerful machine-learning approach, RNA expression and gene variant and fusion information can be combined into one molecular test that is run on a single RNA sequencing platform to provide clinically useful information. Ultimately, this should help more thyroid nodule patients avoid unnecessary surgery. Efforts are already underway to apply this approach to a larger study cohort."

Other Afirma GEC-related posters presented at the ATA conference included a review of long-term outcome studies for the Afirma GEC. Among the three studies with over a year of follow-up, the majority of patients - 85 percent - who had Afirma GEC-benign results following indeterminate cytopathology continued to avoid surgery and be monitored instead. Additionally, researchers from Scripps Clinic/Scripps Green Hospital reported that their use of the Afirma GEC during a five-year period led to a significant reduction (23.6 percent) in surgery recommendations for indeterminate thyroid nodules.

"Thyroid cancer has become a poster child for overtreatment in medicine," said Bonnie Anderson, Veracyte's president and chief executive officer. "The evidence presented at the 2016 ATA conference shows that the Afirma GEC is truly changing care for patients, helping them avoid surgeries they do not need, along with the lifelong implications of that surgery, while also removing costs from the healthcare system. We believe our novel approach also holds promise for providing additional clinically useful cancer-related information to physicians - in thyroid and potentially other cancers."

More information about Veracyte's participation at the ATA conference can be found at www.afirma.com/ata2016.

To date, Veracyte has received more than 270,000 fine needle aspiration (FNA) patient samples and has performed over 60,000 Afirma GEC tests on those deemed inconclusive by cytopathology. The genomic test is supported by more than 20 published studies and is recommended in leading clinical practice guidelines. The Afirma GEC is covered by Medicare and most leading private insurance companies, which collectively represent approximately 185 million Americans.

About Afirma

Among the approximately 525,000 patients who undergo an FNA procedure each year to evaluate potentially cancerous thyroid nodules, up to 30 percent of results are inconclusive. Historically, most of these patients have been directed to surgery for a more definitive diagnosis. The Afirma GEC is proven to identify, with a high degree of accuracy (negative predictive value of > 94 percent), patients whose thyroid nodules are benign so that they may be monitored in lieu of diagnostic surgery. The genomic test is the core component of Veracyte's Afirma Thyroid FNA Analysis, a comprehensive solution for improved thyroid nodule assessment. 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 (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 185 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 2015, the company launched the Percepta® Bronchial Genomic Classifier, a test to evaluate patients with lung nodules that are suspicious for cancer, which has already received draft Medicare coverage. In the fourth quarter of 2016, Veracyte plans to launch its second pulmonology product, the Envisia™ Genomic Classifier, to improve diagnosis of 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 2016 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; the size of the market opportunity for our Percepta Bronchial Genomic Classifier; our ability to successfully achieve adoption of and reimbursement for our Percepta Bronchial Genomic Classifier; the amount the use of the Percepta Bronchial Genomic Classifier is able to reduce invasive procedures and reduce healthcare costs; 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 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, 2016. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.