

March 16, 2016

New Data Show That Veracyte's Afirma® Gene Expression Classifier Reduces Unnecessary Thyroid Surgeries and Costs During Long-Term Follow-Up

SOUTH SAN FRANCISCO, Calif., March 16, 2016 /PRNewswire/ -- <u>Veracyte, Inc.</u> (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, announced publication of data demonstrating that the Afirma Gene Expression Classifier (GEC) reduces unnecessary surgeries in thyroid cancer diagnosis during long-term clinical follow-up. The study is the first to use a national healthcare claims database to determine the real-world impact of the genomic test on patient care and to quantify the costs associated with thyroid surgery. The findings appear online in the journal <u>Current</u> <u>Medical Research & Opinion</u>.

The Afirma GEC is used to identify patients whose thyroid nodules are benign, among those deemed indeterminate following traditional cytopathology evaluation, so that they may avoid diagnostic surgery.

"Our findings demonstrate that a benign Afirma GEC result was as reliable and durable as a benign cytopathology result when patients were followed for a clinically meaningful amount of time," said Joseph Singer, M.D., chief medical officer of <u>HealthCore</u> and lead author of the Veracyte-sponsored study. "Our results suggest that the genomic test may have substantial utility in improving health outcomes by enabling patients to avoid unnecessary surgery and by reducing payer and patient healthcare costs."

Researchers used the HealthCore Integrated Research Environment (HIRE) database, a nationally representative database of Blue Cross Blue Shield plan medical claims to compare outcomes during follow-up of 201 patients with benign Afirma GEC results to a matched control group of 603 patients with benign cytopathology results. They found that, over an average follow-up period of 20 months - and up to three years, Afirma GEC-benign patients were no more likely to undergo thyroid surgery than the control group (11.4 percent vs. 10.1 percent). The rate of ultrasound follow-up examinations was also similar among the Afirma GEC-benign patients (60.2 percent), compared to the cytopathology-benign group (61.7 percent).

The researchers also found that the total cost of thyroid surgery and related clinical follow-up for six months following surgery was \$21,371 - higher than previously used to model cost savings from use of the genomic test.

"This study underscores the significant real-world impact the Afirma GEC is having on patient care and helps to further establish our test as the new standard of care in thyroid cancer diagnosis," said Bonnie Anderson, president and chief executive officer of Veracyte. "Moreover, these results reinforce the significant potential for precision medicine tests such as the Afirma GEC to transform disease diagnosis, benefitting patients, physicians and the healthcare system."

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 (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 nearly 180 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 <u>www.veracyte.com</u>.

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 Annual Report on Form 10-K for the year ended December 31, 2015. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forwardlooking statements.

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