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## **New Study Supports Use of Veracyte's Medullary Thyroid Cancer Classifier as Part of Its Comprehensive Afirma Solution**

SOUTH SAN FRANCISCO, Calif., March 22, 2016 /PRNewswire/ -- [Veracyte, Inc.](#) (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, announced that data from a large, prospective clinical study demonstrate the accuracy of the company's medullary thyroid cancer (MTC) classifier and its potential - when used with the Afirma<sup>®</sup> Gene Expression Classifier (GEC) - to provide a more clinically useful way to diagnose this aggressive cancer preoperatively, compared to traditional methods. The findings are published online in the journal [Thyroid](#).

Researchers analyzed MTC classifier results for 10,488 thyroid nodule fine needle aspiration (FNA) samples whose cytopathology results were indeterminate, suspicious for cancer or malignant. Among the 43 cases that tested positive for MTC, all but one were confirmed as positive by surgery or biochemistry, yielding a positive predictive value of 98 percent. In contrast, previously reported data show that screening with a blood-based biomarker (calcitonin) has a positive predictive value of only 10-40 percent. Of the MTC cases identified by the genomic test in the current study, only 19 (44 percent) were deemed suspicious for MTC by cytopathology.

"Our findings suggest that the MTC classifier specifically identifies MTC where it is often missed by cytopathology, allowing patients to receive the correct thyroid surgery the first time. It also avoids false positives that can lead to unnecessary, extensive surgeries in patients without MTC," said Richard Kloos, M.D., senior medical director, endocrinology, at Veracyte and lead author of the study. "These results support use of the MTC classifier with our Afirma GEC to improve diagnosis of MTC."

While relatively rare, MTC is responsible for a significant portion (up to 13.5 percent) of thyroid cancer deaths and typically requires more aggressive surgical treatment. Veracyte's MTC classifier is used in conjunction with the company's Afirma GEC, which identifies patients whose thyroid nodules are benign among those deemed indeterminate using cytopathology. The MTC classifier is also used when cytopathology results indicate malignancy or suspicion for cancer. In both cases, the test informs the MTC status of patients who are likely heading to surgery.

"Our Afirma GEC is already becoming a new standard of care in thyroid diagnosis, where it is helping patients avoid unnecessary surgery - and reducing healthcare costs - when their thyroid nodules are benign," said Bonnie Anderson, Veracyte's president and chief executive officer. "As part of the Afirma GEC, our medullary thyroid cancer classifier helps ensure that patients heading to surgery for suspected cancer get the right surgery. This further underscores the clinical value that our Afirma solution delivers to patients, physicians and the healthcare system."

### **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 [www.veracyte.com](http://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; 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 forward-looking statements.

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