



April 2, 2016

## **Clinical Utility of Veracyte's Afirma® Gene Expression Classifier Demonstrated in Multiple Studies Presented at ENDO 2016**

### **-- Study Advancing Genomic-Level Understanding of Hürthle Lesions Also Presented --**

SOUTH SAN FRANCISCO, Calif., April 2, 2016 /PRNewswire/ -- [Veracyte, Inc.](#) (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, announced findings from two new studies demonstrating the clinical utility of the Afirma Gene Expression Classifier (GEC). The genomic test is used to rule out cancer in thyroid nodules deemed indeterminate (not clearly benign or malignant) following traditional cytopathology evaluation so that these patients can potentially avoid an unnecessary surgery. The findings were presented today at ENDO 2016, the annual meeting of the Endocrine Society, being held April 1-4 in Boston.

In the first study, Veracyte researchers conducted a systematic review of published data through March 2016 to determine the impact of the Afirma GEC on patient care. Among the 13 studies evaluated, which involved 1,842 patients with Afirma GEC results, the researchers found that 833 patients (45 percent) had "benign" Afirma GEC results, of which 87 (10 percent) went to surgery. Using historical, control-group surgery rates for indeterminate thyroid nodules - recorded in three of the studies - the researchers concluded that use of the Afirma GEC resulted in a 25 percent lower overall surgery rate among all patients with benign or suspicious Afirma GEC results in the 13 studies. Follow-up of Afirma GEC benign nodules was reported in six studies for 457 patients. The median follow-up ranged from 7 to 26 months, during which 393 patients (86 percent) with Afirma GEC benign results had avoided surgery.

"Our findings demonstrate the significant positive, real-world impact that the Afirma GEC is having on patient care," said Richard T. Kloos, M.D., senior director of endocrinology at Veracyte and lead author of the study. "Specifically, these data show that, across a range of clinical settings, the test is helping physicians improve care by avoiding unnecessary diagnostic surgery for their patients. This is important because these surgeries are invasive, costly and often subject patients to lifelong daily thyroid hormone medication."

In the second study, researchers at the University of North Dakota School of Medicine and Health Sciences evaluated the impact of the Afirma GEC on patient care at a local community hospital and found that one patient avoided surgery for every two genomic tests performed. The findings were based on a retrospective review of medical records for 66 patients with Afirma GEC testing results for thyroid nodules that were deemed indeterminate by cytopathology, between April 1, 2012 and October 31, 2014.

"The studies presented today further establish the Afirma GEC as a new standard of care in thyroid cancer diagnosis," said Bonnie Anderson, Veracyte's president and chief executive officer. "Since the test's launch in 2011, we estimate that it has helped more than 20,000 patients avoid an unnecessary thyroid surgery and has provided hundreds of millions of dollars in savings to the healthcare system."

In a separate study presented at ENDO 2016, Veracyte scientists used deep RNA sequencing and other approaches to identify evidence of genomic instability on a subset of Hürthle cell tumors, which may not be observable through histopathological review. The researchers concluded that the findings suggest the potential utility of deep RNA sequencing to help to diagnose this often difficult to detect type of thyroid neoplasm.

#### **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.

Veracyte, Afirma, Percepta, the Veracyte logo, and the Afirma logo are trademarks of Veracyte, Inc.

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/clinical-utility-of-veracytes-afirma-gene-expression-classifier-demonstrated-in-multiple-studies-presented-at-endo-2016-300244933.html>

SOURCE Veracyte

News Provided by Acquire Media