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Veracyte Announces Publication of Data Demonstrating Analytical and Clinical Validity of Its Afirma® BRAF Malignancy Classifier

SOUTH SAN FRANCISCO, Calif., Feb. 5, 2015 /PRNewswire/ -- Veracyte, Inc. (Nasdaq: VCYT) today announced the publication of data demonstrating the analytical and clinical validity of Afirma® BRAF, the company's malignancy classifier for identifying BRAF V600E mutation status among thyroid nodule biopsies. The data, which appear in the current issue of *Pacific Symposium on Biocomputing*, confirm that the Afirma RNA-based classifier detects the BRAF V600E mutation with high diagnostic accuracy.

BRAF V600E mutation is often predictive for papillary thyroid cancer (PTC), the most common thyroid malignancy. Preoperative identification of this mutation in thyroid nodule fine needle aspiration (FNA) biopsies may enable physicians to better assess individual patients' risk of cancer and determine the most appropriate surgical strategy, such as whether to perform a total or partial thyroidectomy. PCR- or sequencing-based DNA analysis is often limited by the need for a DNA quantity that is difficult to procure from an FNA biopsy.

"We believe these data should provide physicians with confidence that our Afirma BRAF test provides an excellent option to help them define surgical strategy for relevant thyroid nodule patients," said Bonnie Anderson, Veracyte's president and chief executive officer. "For those patients who are headed to surgery based on initial cytopathology or results from the Afirma Gene Expression Classifier (GEC), our Afirma BRAF test can have an impact by helping to better inform the most appropriate surgical strategy without the need for an additional FNA."

In the new study, researchers evaluated 535 FNA samples using both the Afirma RNA-based classifier and a sensitive, standard PCR DNA-based test. The Afirma BRAF RNA-based classifier accurately determined the presence or absence of the BRAF V600E DNA mutation with equal performance, but with a lower non-diagnostic rate than the DNA-based test (7.6 percent vs. 24.5 percent). In addition, the Afirma BRAF classifier has broader clinical utility: Because it uses a genomic expression signature associated with altered BRAF signaling, it has the potential to detect BRAF mutations other than V600E.

The Afirma Malignancy Classifiers - which comprise genomic tests for medullary thyroid cancer (MTC) and the BRAF mutation - are part of the Afirma Thyroid FNA Analysis. This solution centers on the Afirma GEC, a genomic test that preoperatively identifies benign nodules among those deemed inconclusive based on cytopathology, thus potentially enabling patients to avoid an unnecessary surgery. The Afirma solution delivers results using a single FNA, enabling patients to avoid returning to the physician's office for additional FNA procedures. Veracyte introduced the Afirma Malignancy Classifiers in May 2014.

About Veracyte

Veracyte (Nasdaq: VCYT) is pioneering the field of molecular cytology, focusing on 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 first commercial solution, the Afirma Thyroid FNA Analysis, centers on the proprietary Afirma Gene Expression Classifier (GEC) to resolve ambiguity in diagnosis and is becoming a new standard of care in thyroid nodule assessment. Since launching its Afirma solution in 2011, Veracyte estimates it has helped approximately 10,000 patients with thyroid nodules avoid unnecessary surgery, reducing healthcare costs by millions of dollars. Afirma is recommended in leading practice guidelines and is covered for more than 140 million lives in the United States, including through Medicare and most commercial insurance plans. Veracyte intends to expand its molecular cytology franchise to other clinical areas, beginning with difficult-to-diagnose lung diseases. The company is in late product development for a genomic test to resolve preoperative ambiguity in lung nodules that are suspicious for cancer. Veracyte is also developing a second product in pulmonology, targeting interstitial lung diseases that include 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 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 the Afirma Gene Expression Classifier, the Afirma Malignancy Classifiers and 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 test; 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 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; 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 September 30, 2014. 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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/veracyte-announces-publication-of-data-demonstrating-analytical-and-clinical-validity-of-its-afirma-braf-malignancy-classifier-300031175.html

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