October 29, 2014

Veracyte, Inc. Announces New Data Supporting Clinical Validity of Afirma® Gene Expression Classifier

Data Presented This Week at the 84th Annual Meeting of the American Thyroid Association

SOUTH SAN FRANCISCO, Calif., Oct. 29, 2014 /PRNewswire/ -- Veracyte, Inc. (Nasdaq: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today announced new data from two studies supporting the use of the company's Afirma Gene Expression Classifier (GEC) to help reduce unnecessary surgeries among patients whose thyroid nodules are indeterminate for cancer following traditional cytopathology review of their fine needle aspiration (FNA) biopsies. The data are being presented at the 84th Annual Meeting of the American Thyroid Association in Coronado, Calif., October 29 - November 2.

A poster entitled, "Long Term Clinical and Imaging Follow-Up of an Office-Based Gene Expression Classifier Used to Manage Thyroid Nodules" (Poster #269), summarized data from a study of patients with thyroid nodules who avoided surgery due to benign Afirma GEC results and were followed for up to three years. All 13 patients in the single-center study remained cancer-free, based on physical exam and ultrasound findings. Additionally, three patients with benign Afirma genomic test results who underwent surgery due to clinical symptoms were confirmed to have benign nodules - further validating the genomic test's accuracy.

"This is the first known study to assess the durability and safety of Afirma GEC results for up to three years," said Dr. Brian Michael of Wellspan Health in Gettysburg, Penn., who will present the new data. "In this relatively small sample, 13 patients who would have previously been referred for surgery were able to safely avoid it. These findings should give physicians further confidence in moving patients with benign Afirma GEC results from diagnostic surgery to routine monitoring."

A poster entitled, "Performance of the Afirma Gene Expression Classifier on Indeterminate Thyroid Fine Needle Aspirates (FNAs) From Large Nodules" (Poster #39), summarized the Afirma GEC's performance on cytologically indeterminate nodules of ≥ 3 cm for which surgical pathology results were subsequently available. All five nodules identified as benign by the Afirma GEC were confirmed by surgery as benign, for a test sensitivity of 100% - underscoring the test's accuracy regardless of nodule size.

"These two new studies add to the growing body of evidence supporting the ability of Veracyte's Afirma GEC to accurately rule out cancer in thyroid nodules that are deemed indeterminate by traditional cytopathology," said Bonnie Anderson, president and CEO of Veracyte. "These findings are consistent with findings from the pivotal clinical validation study published in the *New England Journal of Medicine* in 2012, and taken together reinforce the Afirma GEC as a new standard for helping thyroid nodule patients avoid unnecessary thyroid surgery and the anxiety, costs and need for lifelong thyroid hormone therapy that can accompany such surgery."

Approximately 525,000 thyroid nodule FNA procedures are performed each year in the United States. FNA samples can be challenging to interpret by cytopathology review and produce indeterminate results in 15% to 30% of cases. Guidelines have traditionally recommended surgery for patients with indeterminate results to assess whether the nodules are benign or malignant. Studies have shown that approximately 70% to 80% of the time, the nodules prove to be benign following surgery.

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 135 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 Afirma 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 June 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.

Veracyte, Afirma, the Veracyte logo, and the Afirma logo are trademarks of Veracyte, Inc. This press release also contains trademarks and trade names that are the property of their respective owners.

Media:
Tracy Morris
650-380-4413
Tracy.Morris@Veracyte.com

Investors:
Angeli Kolhatkar
Burns McClellan, Inc.
212-213-0006
akolhatkar@burnsmc.com

SOURCE Veracyte

News Provided by Acquire Media