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Veracyte Presents New Data on Gene Variants and Fusions In Thyroid Cancer Diagnosis

SOUTH SAN FRANCISCO, Calif., Oct. 21, 2015 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today announced findings from a new study of the largest panel of thyroid cancer-associated gene alterations to date. The results showed that well-established and more recently discovered molecular alterations that are associated with thyroid cancer were found in both confirmed benign and malignant nodules. This suggests that more research is needed to understand how gene variant and fusion information can best be used to guide physician decision-making in thyroid cancer diagnosis. The findings were presented today at the 15th Annual International Thyroid Congress (ITC) and 85th Annual Meeting of the American Thyroid Association (ATA), in Lake Buena Vista, Fla.

Veracyte researchers developed a test panel of 851 variants and 133 fusions in 524 genes, based on known gene alterations associated with thyroid cancer, including those identified by The Cancer Genome Atlas (TCGA) project.* They then used RNA sequencing to determine the presence of these gene alterations in 76 malignant thyroid samples, representing a variety of cancer subtypes, and in 75 benign samples. Consistent with other studies on DNA-based mutations, the researchers found that gene alterations appeared in only 50 percent of the cancerous samples (sensitivity). At the same time, 20 percent of the benign thyroid samples harbored gene alterations (*i.e.*, 80 percent specificity).

"As gene alterations associated with thyroid cancer become more common in the literature, physicians are increasingly interested in how to use this information in clinical practice," said Richard Kloos, M.D., Veracyte's senior medical director, endocrinology, who presented the data. "Our findings suggest that caution should be exercised, particularly in using gene variant and fusion panels on their own to rule out or rule in cancer in thyroid nodule patients.

"Our results also underscore the tremendous need to clarify the role that gene alterations *can* potentially play in thyroid cancer diagnosis. We look forward to pursuing this question more fully and to exploring how gene variant and fusion data, based on powerful RNA sequencing, could potentially be used with our Afirma® Gene Expression Classifier (GEC) to extract additional, clinically useful information from thyroid nodule samples."

Veracyte's Afirma GEC uses RNA-based gene expression and is proven in rigorous clinical studies to identify benign thyroid nodules among those deemed indeterminate by cytopathology, enabling these patients to potentially avoid an unnecessary surgery. 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.

For the study presented today, Veracyte researchers evaluated the presence of gene variants and fusions using RNA sequencing, which measured gene alterations found only in genes expressed in thyroid nodules. "We believe RNA sequencing offers a potentially powerful approach to evaluating gene variants and fusions because it looks at biological activity associated with these gene alterations, which may be more indicative of disease processes, compared to DNA-based gene alterations, which may never be expressed in the tissue of interest. We continue to evaluate the impact of this richer genomic information in enhancing physician-patient decision making," said Dr. Kloos.

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 approximately 150 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 t 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.

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 Quarterly Report on Form 10-Q for the quarter ended June 30, 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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* The Cancer Genome Atlas (TCGA) is a collaboration between the National Cancer Institute (NCI) and National Human Genome Research Institute (NHGRI) that aims to generate comprehensive, multi-dimensional maps of the key genomic changes in major types and subtypes of cancer.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/veracyte-presents-new-data-on-gene-variants-and-fusions-in-thyroid-cancer-diagnosis-300163735.html

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