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New Data Suggest Veracyte's Molecular Test Improves Accuracy of Thyroid Nodule Diagnosis Using Fine Needle Aspirate (FNA) Samples

South San Francisco, Calif.--- PRNewswire ---Veracyte, Inc., a molecular diagnostics company pioneering the emerging field of molecular cytology, announced that initial data from its large-scale, prospective, multi-center clinical trial were presented today at the 14th International Thyroid Congress, held in Paris, France. The findings showed that the company's molecular test classified inconclusive thyroid nodule fine needle aspirates (FNA) as benign with a high degree of accuracy, showing potential to help thousands of patients each year avoid surgery. These results demonstrate Veracyte's ability to use molecular testing to improve the diagnostic accuracy of FNA samples, enhancing the utility of this minimally invasive alternative to surgical diagnosis. Veracyte also announced that an article describing the company's rigorous scientific and clinical approach to development of its molecular test for use on cytology samples has been published online in the Journal of Clinical Endocrinology & Metabolism and will appear in the publication's December print issue.

In today's presentation at the International Thyroid Congress, lead author Bryan R. Haugen, M.D., Professor of Medicine and Pathology Head, Division of Endocrinology, Metabolism & Diabetes, at the University of Colorado, shared early data from the multi-center study, involving more than 40 community and academic sites. The researchers found that among 66 thyroid FNA samples, including 43 indeterminate samples, for which surgical pathology results were known, Veracyte's test had a negative predictive value (NPV) greater than 95 percent when compared to the gold standard of two blinded expert histopathology reviews. The multi-center clinical trial is ongoing, and results of the confirmatory performance study are expected to be published next year.

"A test with this high of a negative predictive value will help doctors rule out malignancy and confidently monitor many patients with ambiguous thyroid nodules, enabling these patients to avoid unnecessary surgery," said Dr. Haugen. Dr. Haugen noted that FNAs are recommended for most patients with thyroid nodules to help determine if the nodules are benign or malignant, but that 15-30 percent of samples have indeterminate cytology results. Many of these patients require surgery for final diagnosis, with the majority proving to be benign. "This molecular classifier is a major advance in our ability to appropriately manage a large number of patients with thyroid nodules," Dr. Haugen added.

In the Journal of Clinical Endocrinology & Metabolism article, the authors demonstrate the ability to develop a molecular test that can accurately classify fine needle aspirate (FNA) samples for a biologically complex disease – in this case, thyroid cancer – despite challenges with sample heterogeneity, coupled with very small quantity and variable quality genomic material.

Elements of the state-of-the-art discovery and development program deployed by Veracyte's scientists and described in the article include: using large numbers of "real world" FNA samples to incorporate into the test the breadth of clinical samples that it may encounter; employing a whole-genome approach to identify genes that best differentiate benignity from malignancy, coupled with machine-learning algorithms and sophisticated statistical approaches to make sense of the large amount of genomic data; and utilizing large, prospective, multi-center clinical studies for discovery and clinical validation.

"These initial data and journal article are strong testaments to our company's ability to develop and effectively apply molecular biomarkers to minimally invasive cytology samples such as fine needle aspirates. By improving the diagnostic accuracy of FNAs, we believe that their utility as an alternative to surgical biopsy is enhanced, thus helping to improve cancer diagnosis and monitoring," said Bonnie Anderson, Veracyte's Cofounder and Chief Executive Officer. "Our ultimate goal is to enable doctors to make better, more efficient treatment decisions that can improve patient care and provide cost savings to the healthcare system."

Ms. Anderson noted that Veracyte plans to begin marketing its thyroid test – branded Afirma™ on a limited basis to several academic centers that have requested early access by the end of this year. Additional commercialization is planned for early 2011. Thyroid cancer is the fastest-growing cancer in the United States, according to the American Cancer Society, which estimates that 44,670 new cases will be diagnosed nationwide this year.

Thyroid nodules, growths of cells in the thyroid gland, are a common clinical problem that occurs more frequently in women and the elderly, and are typically benign. An estimated 450,000 thyroid biopsies are performed each year in the U.S.

About Veracyte
Veracyte, Inc., based in South San Francisco, Calif., is pioneering the emerging field of molecular cytology, applying molecular biomarkers to cytology samples in order to improve cancer diagnosis by clarifying indeterminate results obtained from current

methods. The company aims to enable doctors to make more informed treatment decisions that improve patient care and provide cost savings to the healthcare system. The company utilizes rigorous science and an extensive, multi-center clinical program throughout discovery and development. Veracyte is privately held and funded by Domain Associates, Kleiner Perkins Caufield & Byers, TPG Biotech and Versant Ventures. For more information, visit www.veracyte.com.

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