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Veracyte Announces Results of Study Assessing Use of BRAF Mutation Testing With Its Afirma® Gene Expression Classifier

South San Francisco, Calif. --- March 12, 2013 --- Veracyte, Inc., a molecular diagnostics company pioneering the emerging field of molecular cytology, today announced new study findings showing that when BRAF V600E mutation testing was conducted on ambiguous thyroid nodule samples that were subsequently classified as benign by the company's Afirma Gene Expression Classifier, no BRAF-positive cases – that would suggest cancer – were found. The study appears online in the *Journal of Clinical Endocrinology & Metabolism.*

"Multicenter, prospective studies have previously established the high accuracy of the Afirma Gene Expression Classifier in identifying patients with inconclusive thyroid nodule biopsies whose nodules are actually benign and can thus safely avoid unnecessary surgery," said Giulia C. Kennedy, Ph.D., chief scientific officer of Veracyte, and an author of the new study. "Our findings showed that testing for BRAF – a gene mutation linked to some thyroid cancers – did not identify any cancer cases among those deemed benign by the Afirma test. Additionally, BRAF mutations were found in only a small portion (30%) of the samples that turned out to be malignant and were classified by the Afirma test as suspicious."

BRAF mutation testing was conducted on 208 thyroid nodule FNA samples that were indeterminate – not clearly benign or malignant following cytopathology (microscope-based) review. These samples had subsequently been tested with the Afirma Gene Expression Classifier as part of a prospective, double-blinded, multicenter (49-site) study. BRAF mutations were found in 10% of indeterminate cases overall, and in just 2.1% and 1.4%, respectively, of the two most common subcategories of indeterminate thyroid nodule biopsies.

The Afirma Gene Expression Classifier measures the expression of 142 genes to reclassify indeterminate thyroid FNA samples as either benign or suspicious for cancer. An additional 25 supplemental genes are used to improve classification of rare cancer subtypes. The Afirma test is the only molecular test clinically validated in prospective, multicenter, double-blinded trials to meet the criteria of National Comprehensive Cancer Network (NCCN) guidelines for safely monitoring nodules in lieu of diagnostic surgery. The test is offered as part of Veracyte's comprehensive Afirma Thyroid FNA Analysis, which combines specialized cytopathology assessment for initial review of thyroid nodule FNAs, with the gene expression test used to clarify inconclusive results. The test is available throughout the U.S. through a global co-promotion partnership with Genzyme, a Sanofi company.

Thyroid cancer is the fastest-increasing cancer in the United States, with 60,220 new cases expected in 2013, according to the American Cancer Society. Approximately 450,000 thyroid nodule FNAs – a minimally invasive procedure to extract cells for examination under the microscope – are performed each year in the U.S. to rule out cancer. However, 15% to 30% of FNA biopsy results are inconclusive, and most physicians recommend thyroid surgery for final diagnosis. Following surgery, however, 70-80% of patients' nodules are diagnosed as benign. These surgeries are invasive, expensive, and typically result in lifelong thyroid hormone replacement therapy for the patient.

About Veracyte

Veracyte, Inc., based in South San Francisco, Calif., is a privately held molecular diagnostics company pioneering the emerging field of molecular cytology. The company discovers, develops and commercializes molecular diagnostic solutions that enable physicians to make more informed treatment decisions early, thus helping patients avoid unnecessary invasive procedures while reducing healthcare costs. Veracyte's first product – the Afirma® Thyroid FNA Analysis – combines specialized cytopathology assessment with the Afirma Gene Expression Classifier, a genomic test that clarifies inconclusive thyroid nodule results as benign or suspicious for cancer. The company has formed a global co-promotion partnership with Genzyme, a Sanofi company, to make the Afirma Thyroid FNA Analysis available throughout the U.S. and, subsequently, globally. Veracyte is currently in the early biomarker discovery phase for lung cancer and interstitial lung diseases. 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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