October 18, 2013

Veracyte Presents Preliminary Data Suggesting Potential for an RNA-Based Gene Expression Test to Detect the BRAF V600E Mutation in Thyroid Nodule Biopsy Samples

Findings Presented at 83rd Annual Meeting of the American Thyroid Association

South San Francisco, Calif. --- October 18, 2013 --- Veracyte, Inc., a molecular diagnostics company pioneering the field of molecular cytology, today announced preliminary study results suggesting the potential for an RNA-based gene expression test to accurately detect the BRAF V600E gene mutation in thyroid nodule fine needle aspiration (FNA) samples. The findings were presented Thursday in a poster session at the 83rd Annual Meeting of the American Thyroid Association (ATA), held in San Juan, Puerto Rico.

"The BRAF V600E mutation has generated a great deal of interest among clinicians, as its presence in a thyroid nodule malignancy may potentially help guide the extent of surgery needed or how aggressively to treat a malignancy," said Giulia C. Kennedy, Ph.D., chief scientific officer at Veracyte and lead author of the study. "Our preliminary findings are encouraging, suggesting that an RNA-based gene expression test can potentially determine the presence or absence of the BRAF V600E mutation with a high degree of accuracy in thyroid nodule FNA samples."

Veracyte researchers developed and assessed a preliminary RNA-based gene expression test on thyroid nodule FNA samples that were deemed by cytopathology as malignant, suspicious for malignancy or indeterminate. They found the gene expression test to be comparable in accuracy to DNA-based PCR testing in detecting the BRAF V600E mutation. Additionally, the researchers were able to extract more genomic material with the gene expression test, versus the DNA-based test, suggesting it could potentially enable better sample utilization and a lower rate of no results due to sample insufficiency.

"We believe these preliminary findings demonstrate a potential opportunity to enhance our Afirma® Thyroid FNA Analysis solution as a comprehensive way to manage thyroid nodules," said Bonnie Anderson, president and chief executive officer of Veracyte. "Specifically, these data suggest that we may be able to provide physicians with additional information pre-operatively that can help further guide their surgical strategy, when surgery is needed. This could potentially compliment our Gene Expression Classifier, which identifies benign thyroid nodule FNA samples among those deemed indeterminate by cytopathology and thus potentially enables these patients to avoid unnecessary surgery. We look forward to exploring this opportunity further."

About Veracyte, Inc.

Veracyte is focused on discovering, developing and commercializing molecular cytology solutions that enable physicians to make more informed treatment decisions at an early stage in patient care, thus helping patients avoid unnecessary invasive procedures while reducing healthcare costs. Veracyte's first commercial solution, the Afirma® Thyroid FNA Analysis, includes the Gene Expression Classifier (GEC). The GEC helps physicians reduce the number of unnecessary surgeries by employing a proprietary 142-gene signature to preoperatively determine whether thyroid nodules previously classified by cytopathology as indeterminate can be reclassified as benign. The clinical utility and cost effectiveness of the GEC have been demonstrated in studies published in peer-reviewed journals and the clinical validity of the GEC has been demonstrated in a study published in The New England Journal of Medicine in 2012. Since the commercial launch of Afirma in January 2011, Veracyte has processed over 50,000 fine needle aspiration (FNA) samples for evaluation using Afirma and has performed more than 10,000 GECs to resolve indeterminate cytopathology results. Veracyte has obtained positive coverage decisions for Afirma from Aetna, Humana, Medicare and UnitedHealthcare. Collectively, these payers represent more than 100 million covered lives. Afirma is marketed and sold in the United States through a global co-promotion agreement with Genzyme Corporation, a subsidiary of Sanofi.