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Long-Term, Multicenter Outcome Study Confirms Clinical Validity and Clinical Utility of Veracyte's Afirma Gene Expression Classifier

South San Francisco, Calif. --- October 23, 2013 --- Data from a new long-term, multicenter study confirm the accuracy of the Afirma Gene Expression Classifier (GEC) in identifying benign thyroid nodule fine needle aspiration (FNA) biopsies among those initially deemed indeterminate, or inconclusive, by cytopathology, Veracyte, Inc. announced today. The findings further support physicians' decision to avoid diagnostic surgery on such patients and monitor them instead – and suggest that this change in clinical practice is occurring. The findings appear online in Journal of Clinical Endocrinology & Metabolism and follow their recent presentation at the 83rd Annual Meeting of the American Thyroid Association.

"Results of this long-term study confirm our previous data showing that, among cytologically indeterminate thyroid nodule FNA samples, when the GEC identifies a nodule as benign, there appears to be a very low risk that cancer is present," said lead author Erik K. Alexander, M.D., of Brigham and Women's Hospital and Harvard Medical School. "This should give physicians further confidence that patients with benign GEC results can be safely monitored, rather than directed to diagnostic surgery. Furthermore, incorporating this test into routine clinical care could significantly reduce the number of patients undergoing unnecessary surgery and thus help minimize the morbidity and costs associated with such surgery."

Researchers at five academic centers followed all thyroid nodule patients who were tested with the Afirma GEC following indeterminate biopsy results based on cytopathology between 2010 and 2013. Among the 339 patients with indeterminate thyroid nodules, the Afirma GEC identified 174 (51%) as benign and, of these, 71 patients were followed clinically for an average of 9 months. Of these 71 patients, only 1 cancer was identified over the course of the study, confirming a high negative predictive value (NPV) for the Afirma GEC of over 95%, and similar to the malignancy risk of a benign cytopathology result. These findings reaffirm data from the initial validation trial published last year in the New England Journal of Medicine. The new study also underscores the clinical utility of the Afirma GEC, as only 6% of patients with nodules identified as benign by Veracyte's test underwent surgery. This is a significant reduction compared to traditional surgical rates for patients with cytologically indeterminate thyroid nodules and is consistent with other data.

In addition to Brigham and Women's Hospital, the centers participating in the study were The Ohio State University College of Medicine, University of Cincinnati College of Medicine, University of Colorado and University of Pennsylvania School of Medicine.

"These new findings confirm the results of our earlier pivotal validation study and further add to the growing body of evidence supporting the clinical validity and clinical utility of the Afirma Gene Expression Classifier in thyroid nodule assessment," said Bonnie Anderson, president and chief executive officer of Veracyte. "By helping patients avoid unnecessary surgery, Afirma is advancing our goal of improving patient care and reducing healthcare costs."

According to the American Cancer Society, thyroid cancer is the fastest-growing cancer in the United States. Approximately 525,000 thyroid nodule FNA procedures were performed in the U.S. in 2011. FNA samples can be challenging to interpret by cytopathology review and produce indeterminate results in 15% to 30% of cases. Current guidelines recommend that patients with indeterminate results be considered for diagnostic surgery 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. These surgeries are invasive, costly and frequently result in lifelong thyroid hormone therapy for the patient.

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.

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Media Contact
Tracy Morris
650-380-4413
tracy.morris@veracyte.com