June 25, 2012

Veracyte Announces Study Results Published Online in New England Journal of Medicine Which Suggest that Its Afirma® Gene Expression Classifier Can Reduce Unnecessary Thyroid Surgeries

Findings Also Presented at ENDO 2012: The 94th Annual Meeting & Expo

Houston, Texas — June 25, 2012 — Veracyte, Inc., a molecular diagnostics company that is pioneering the emerging field of molecular cytology, today announced results from a large, prospective, multicenter study, which demonstrated the potential for the Afirma® Gene Expression Classifier, a gene expression test, to reduce the large number of unnecessary surgeries in thyroid cancer diagnosis by more than half.

The results are being shared during a late-breaking data presentation at The Endocrine Society's ENDO 2012: The 94th Annual Meeting & Expo in Houston, Texas, and coincide with online publication by the *New England Journal of Medicine*. The study is scheduled to appear in the journal's August 23, 2012 print issue.

The two-year study involved 265 indeterminate thyroid FNA samples collected from 49 academic and community sites around the United States. The findings showed that the Afirma Gene Expression Classifier can reclassify as "benign" — with a high degree of accuracy – thyroid nodule fine needle aspirate (FNA) samples that were originally deemed inconclusive by cytopathology review using a microscope. When applied to the major categories of indeterminate samples (those with cytology labeled: "atypical of an undetermined significance" or "follicular neoplasm"), the genomic test had a negative predictive value (NPV) of 95 and 94 percent, respectively. Overall, the NPV was 93 percent, based on the study's cancer prevalence rate of 32 percent. The overall NPV increases to 95 percent when a lower cancer prevalence rate of 24 percent, which is more representative of thyroid cases across the U.S., is applied. The test had a sensitivity of 92 percent and a specificity of 52 percent.

"Presently, patients with cytologically indeterminate thyroid nodules are usually referred for thyroid surgery to ensure that thyroid cancer is not present," said co-principal study investigator Erik K. Alexander, M.D., of Brigham and Women's Hospital and Harvard Medical School. "The gene expression test, when benign, should now enable physicians to consider recommending against surgery and confidently monitor patients in a more conservative fashion. Approximately half of all patients with indeterminate thyroid nodule cytology will have a benign gene expression test. This means that tens of thousands of thyroid nodule patients in the U.S. each year can potentially be spared a thyroid surgery they do not need."

Indeterminate thyroid nodule cytology results are a significant problem in thyroid cancer diagnosis. Thyroid nodules are common and, while most are benign, 5-15 percent prove malignant, prompting diagnostic evaluation, typically via FNA sampling. Approximately 450,000 thyroid nodule FNAs – a minimally invasive procedure to extract cells for examination under a microscope — are performed in the U.S. each year. Such cytology samples, however, produce indeterminate results in 15-30 percent of cases, or approximately 100,000 patients each year in the U.S. Current medical guidelines recommend that most of these patients have all or part of their thyroids removed for final diagnosis. However, the majority (70-80 percent) prove to have benign conditions. These surgeries are invasive, costly and typically result in lifelong hormone therapy for the patient. Additionally, these patients are unnecessarily exposed to a 2-10 percent risk of surgical complications.

"Our results showed that the gene expression test can substantially reclassify otherwise inconclusive thyroid nodule cytology results," said co-principal study investigator Bryan R. Haugen, M.D., professor of medicine and pathology head, Division of Endocrinology, Metabolism & Diabetes at the University of Colorado. "When the gene expression test is benign, this conveys the same level of predictive accuracy comparable to patients who had a benign cytopathology result."

An accompanying *New England Journal of Medicine* editorial concludes, "In this era of focusing on high-quality outcomes at lower cost, this new gene-expression classifier test is a welcome addition to the tools available for informed decision making about the management of thyroid nodules."

The two-year study enrolled 3,789 patients and prospectively collected 4,812 thyroid FNA samples from nodules larger than or equal to 1.0 cm. Samples were simultaneously collected for local cytopathology analysis, as well as for the study. If the local cytopathology result was indeterminate, the study sample was then analyzed using the gene expression test. Thyroid surgery

was performed based on the judgment of the treating physician who was blinded to the genomic test results. At completion of the study, the gene expression test results were compared to gold-standard histopathology diagnosis provided by two blinded experts following review of surgically removed tissue samples.

This rigorous study is the largest of its kind ever conducted to assess thyroid diagnosis and further confirms the strength and utility of our Afirma Gene Expression Classifier to help prevent avoidable surgeries," said Bonnie Anderson, Veracyte's cofounder and chief executive officer. "Ultimately, these results should underscore the potential of the genomic test to help physicians make more informed treatment decisions early, thus improving patient care and helping to take significant costs out of the healthcare system."

About the Afirma Gene Expression Classifier
Veracyte's Afirma Gene Expression Classifier evaluates the expression patterns of 142 genes to classify indeterminate thyroid nodule FNA samples as benign or suspicious for cancer. The test also uses 25 supplemental genes to improve classification of rare cancer subtypes. The Afirma Gene Expression Classifier is part of Veracyte's comprehensive Afirma Thyroid FNA Analysis, which combines cytopathology specialist assessment for initial review of thyroid nodule FNAs, with the gene expression test used to clarify inconclusive results. The Afirma Gene Expression Classifier is now covered for Medicare patients nationwide and has become clinically available across the U.S. in the last year.

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 disease diagnosis by clarifying indeterminate results obtained from current methods. The company aims to enable doctors to make more informed treatment decisions early, thus improving patient care and providing cost savings to the healthcare system. The company utilizes rigorous science and an extensive, multicenter clinical program throughout discovery and development. Veracyte's first product – the Afirma® Thyroid FNA Analysis – combines specialist cytopathology assessment with the Afirma Gene Expression Classifier, a genomic test that clarifies inconclusive thyroid nodule cytology 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.

###

Broadcast/Online Media: Supporting video footage, including an interview with a co-principal investigator, is available via download at www.NewsInfusion.com/events/veracyteNEJM. For more information or hard copies: News Broadcast Network, 646-839-5114 or dschwartzberg@newsbroadcastnetwork.com.

Media Contact:
Tracy Morris
650-473-1272 (o)
650-380-4413 (c)
tracy.morris@veracyte.com

Send Veracyte media related inquiries to media@veracyte.com.