



July 17, 2012

## **New Study Suggests That Use of Veracyte's Afirma® Gene Expression Classifier Helps to Significantly Reduce Surgeries in Patients with Ambiguous Thyroid Nodule Cytology Results**

South San Francisco, Calif. and Cambridge, Mass. — July 17, 2012 — [Veracyte, Inc.](#), a molecular diagnostics company pioneering the emerging field of molecular cytology, and [Genzyme](#), a Sanofi company (EURONEXT: SAN and NYSE: SNY), today announced the publication of new data suggesting that routine clinical use of Veracyte's Afirma® Gene Expression Classifier helps to significantly reduce the number of surgeries performed on patients whose thyroid nodule cytology results are not clearly benign or malignant following traditional evaluation.

The study found that when the genomic test reclassified "indeterminate" thyroid nodule fine needle aspiration (FNA) samples as "benign" — which data show it did approximately half the time — surgery rates for those patients decreased by 90%, compared to traditional surgery rates for patients with indeterminate cytology without molecular testing. The findings were published online in the journal *Thyroid* and underscore the clinical utility of the Afirma Gene Expression Classifier in helping to reduce thyroid surgeries and related costs as part of thyroid cancer diagnosis.

Thyroid cancer is the fastest-increasing cancer in the United States, with an estimated 56,460 new cases expected in 2012, according to the American Cancer Society. Approximately 450,000 thyroid nodule FNAs — a minimally invasive procedure to extract cells for examination under a microscope — are performed each year in the U.S. to rule out cancer. In up to 30% of cases, the results are ambiguous, with current guidelines recommending surgery for most of these patients to remove all or part of their thyroid for final diagnosis. This approach is invasive, costly and can result in lifelong thyroid hormone therapy for the patients. Most of these patients (70-80%), however, turn out to have benign conditions.

In the new study, the surgery rate for patients with inconclusive thyroid nodule FNAs fell from a traditional rate of 74% for patients with inconclusive thyroid nodule FNAs to 7.6% among such patients who subsequently had a benign Afirma Gene Expression Classifier result. The latter rate was also similar to the historically reported rate (9%) of surgery for patients whose thyroid nodules were deemed benign using traditional methods.

"Our findings showed that a benign result on the Afirma Gene Expression Classifier led physicians and patients to select observation and monitoring in most cases, rather than moving straight to surgery. Applied in routine clinical practice, this approach should significantly reduce the number of diagnostic surgeries performed on patients with ambiguous FNA cytology results," said Dr. Bryan McIver, consultant endocrinologist at Mayo Clinic in Rochester, Minn., and co-principal investigator of the new study. "Our data suggest that physicians in this study were sufficiently confident in the reliability of the molecular test to be comfortable monitoring patients with benign genomic test results, rather than sending them to surgery for diagnosis. This could ultimately save thousands — perhaps even tens of thousands — of patients each year from unnecessary thyroid surgery."

The findings were based on the evaluation of surgery decisions for 368 patients treated by 51 endocrinologists at 21 sites around the country. Community and academic centers that used the Afirma Gene Expression Classifier in routine clinical practice identified consecutive eligible patients who had inconclusive thyroid nodule FNA cytology results and for whom benign genomic test results had been reported. Surgery-decision data were collected between September 2011 and March 2012.

"These results suggest that use of the Afirma Gene Expression Classifier helps to significantly reduce surgeries in patients with inconclusive thyroid nodule samples," said Bonnie Anderson, cofounder and chief executive officer of Veracyte. Ms. Anderson noted that clinical validation studies have demonstrated the test's ability to reclassify inconclusive thyroid nodule FNA samples as "benign" with a high degree of accuracy.

The Afirma Gene Expression Classifier is part of Veracyte's comprehensive Afirma Thyroid FNA Analysis. This solution combines specialized cytopathology assessment for initial review of thyroid nodule FNAs, with the gene expression test used to clarify inconclusive results. A recent economic impact study, published in the *Journal of Clinical Endocrinology & Metabolism*, concluded that routine use of the Afirma Gene Expression Classifier in the U.S. would prevent tens of thousands of avoidable surgeries each year and would provide more than \$600 million in direct medical savings over 5 years. The Afirma Gene Expression Classifier is now covered for Medicare patients nationwide and is available throughout the U.S. through a global co-promotion partnership with Genzyme, a Sanofi company and one of the world's leading biotechnology companies.

“We believe these new findings will further strengthen our offering of a complete solution for thyroid patients, which includes the Afirma Thyroid FNA Analysis for assessment of thyroid nodules, and Thyrogen® for the management of patients diagnosed with thyroid cancer,” said Alicia Secor, Genzyme’s vice president and general manager of Endocrinology.

Genzyme is an established leader in endocrinology globally, developing and marketing Thyrogen® (thyrotropin alfa for injection) for patients with well-differentiated thyroid cancer. Thyrogen® is used as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging. Thyrogen® is also approved in the U.S. and Europe as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of metastatic thyroid cancer.

### **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 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](http://www.veracyte.com).

### **About Genzyme, a Sanofi Company**

Genzyme has pioneered the development and delivery of transformative therapies for patients affected by rare and debilitating diseases for over 30 years. The company accomplishes its goals through world-class research and with the compassion and commitment of its employees. With a focus on rare diseases and multiple sclerosis, the company is dedicated to making a positive impact on the lives of the patients and families it serves. That goal guides and inspires Genzyme every day. Genzyme’s portfolio of transformative therapies, which are marketed in countries around the world, represents groundbreaking and life-saving advances in medicine. As a Sanofi company, Genzyme benefits from the reach and resources of one of the world’s largest pharmaceutical companies, with a shared commitment to improving the lives of patients. Learn more at [www.genzyme.com](http://www.genzyme.com).

### **About Sanofi**

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients’ needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Veracyte® and Afirma® are registered trademarks of Veracyte, Inc. Genzyme® and Thyrogen® are registered trademarks of Genzyme Corporation. All rights reserved.

### **Sanofi Forward Looking Statements**

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group’s ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2011. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise*

*any forward-looking information or statements.*

# # #

**Media Contacts:**

For Veracyte:

Tracy Morris

650-380-4413

[tracy.morris@veracyte.com](mailto:tracy.morris@veracyte.com)

For Genzyme:

Ingrid Esser

617-768-6699

[ingrid.esser@genzyme.com](mailto:ingrid.esser@genzyme.com)

Send Veracyte media related inquiries to [media@veracyte.com](mailto:media@veracyte.com).