



August 29, 2012

## **Veracyte Receives New York State License for Afirma® Gene Expression Classifier**

### **Veracyte and Genzyme Also Announce that Memorial Sloan-Kettering Cancer Center is Among the State's First Institutions to Offer Genomic Test to Patients with Inconclusive Thyroid Nodule Results**

South San Francisco, Calif. and Cambridge, Mass. --- August 29, 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 that the New York State Department of Health has issued a license enabling Veracyte's Afirma® Gene Expression Classifier to be offered to patients in the state. The companies also announced that Memorial Sloan-Kettering Cancer Center will become one of the first medical institutions in the state to offer patients the genomic test, which helps resolve inconclusive thyroid nodule results following traditional evaluation of fine needle aspiration (FNA) samples.

"We are delighted that the Afirma Gene Expression Classifier will now be available to physicians and their patients in New York State and that Memorial Sloan-Kettering is among the first in the state to offer our test," said Bonnie Anderson, Veracyte's cofounder and chief executive officer. "These milestones underscore the clinical need for and strength of the clinical data behind our test. Our goal is to help identify patients whose thyroid nodules are actually benign so that they may avoid unnecessary, invasive surgery."

Thyroid cancer is the fastest-increasing cancer in the United States, with 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 the microscope – are performed each year in the U.S. to rule out cancer. Up to 30% of the time, the results are inconclusive, and current protocols typically recommend thyroid surgery for final diagnosis. Following surgery, however, 70-80% of patients turn out to have benign nodules.

The Afirma Gene Expression Classifier measures the expression of 142 genes to reclassify ambiguous thyroid FNA samples as either benign or suspicious for cancer. A clinical validation study, published recently in the *New England Journal of Medicine*, showed that when applied to the major categories of indeterminate thyroid samples, the test reclassified the samples as benign with greater than 94% accuracy.

The Afirma Gene Expression Classifier 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 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 look forward to bringing to New York endocrinologists and thyroid patients a complete solution, which includes the Afirma Thyroid FNA Analysis for thyroid nodule assessment 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 in the follow up of patients with well-differentiated thyroid cancer. 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).