



April 16, 2012

## **Genzyme and Veracyte Announce Expanded U.S. Availability of the Afirma® Thyroid FNA Analysis for Improved Thyroid Nodule Diagnosis**

Cambridge, Mass. and South San Francisco, Calif. --- Genzyme, a Sanofi company (EURONEXT: [SAN](#) and NYSE: [SNY](#)), and Veracyte, Inc., a molecular diagnostics company pioneering the emerging field of molecular cytology, today announced that the Afirma® Thyroid FNA Analysis, an innovative approach for improved thyroid nodule diagnosis, is now available to patients across the United States.

The Afirma® Thyroid FNA Analysis combines expert cytopathology assessment of thyroid nodule fine needle aspiration (FNA) samples, with the Afirma® Gene Expression Classifier, a novel genomic test, used to resolve inconclusive results and thus help patients whose nodules are actually benign avoid unnecessary surgery. Two independent clinical studies to date have shown that the Afirma® Gene Expression Classifier can reclassify patients with indeterminate thyroid FNA results as “benign” with the same degree of accuracy as a benign cytopathology diagnosis.

Thyroid cancer is the fastest-growing cancer in the U.S., with an estimated 56,460 new cases expected in 2012, according to the American Cancer Society. An estimated 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 to rule out cancer. Thyroid nodule FNAs are challenging to interpret, however, producing ambiguous results in up to 30 percent of cases. Current guidelines recommend that most patients with ambiguous results undergo thyroid resection for a definitive diagnosis. Post-surgical results, however, show that only 20–30 percent of these patients have cancer.

“Until now, most patients with “indeterminate” thyroid nodules based on cytology went to surgery to help ensure that a cancer was not missed,” said Dr. Bryan Haugen, professor of medicine and pathology at the University of Colorado School of Medicine. “Now, the Afirma® Gene Expression Classifier can potentially help tens of thousands of patients with inconclusive thyroid nodules each year avoid unnecessary surgery and improve patient outcomes.”

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.

“The addition of the Afirma® Thyroid FNA Analysis represents a strong strategic fit for our Thyrogen business and addresses a significant unmet need. The combined offering represents a complete personalized solution that really advances thyroid nodule assessment and the value of Thyrogen® in the management of patients diagnosed with thyroid cancer,” said Genzyme's VP and GM of Endocrinology, Alicia Secor. “We expect many patients with thyroid nodules will want to ask their physicians about the Afirma® Thyroid FNA Analysis at the beginning of the diagnostic process.”

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 test is now covered for Medicare patients nationwide.

### **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. We accomplish our goals through world-class research and with the compassion and commitment of our employees. With a focus on rare diseases and multiple sclerosis, we are dedicated to making a positive impact on the lives of the patients and families we serve. That goal guides and inspires us 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](#)).

## 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 expert 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 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).

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## 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.*

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