

PRESS RELEASE



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Media Contact:  
Ingrid Mitchell  
(617) 768-6699  
Ingrid.Mitchell@genzyme.com

## **U.S. Prescribing Information for Thyrogen Revised to Include Use of Wider Range of Radioiodine in Patients**

*Revised label will facilitate use of Thyrogen to greater number of patients for postoperative thyroid remnant ablation*

CAMBRIDGE, Mass. – [Genzyme](#), a Sanofi company (EURONEXT: SAN and NYSE: SNY), today announced the Food and Drug Administration (FDA) approved revised prescribing information for the use of Thyrogen<sup>®</sup> (thyrotropin alfa for injection) to widen the dose range of radioiodine (RAI) when used for thyroid remnant ablation. Thyrogen is used before radioiodine treatment to enhance uptake of the radiotracer and allows patients to start and continue taking their thyroid hormone replacement therapy thus avoiding the untoward effects associated with hypothyroidism. Previously the amount of radioiodine was fixed at 100 mCi, whereas physicians may now select a dose from the range of 30-100 mCi.

“The incidence of thyroid cancer is rapidly increasing in the United States,” said Bryan Haugen, M.D., Professor of Medicine at the University of Colorado and immediate past President of the American Thyroid Association. “Today’s FDA revision to widen the administered dose range of RAI for patients being prepared for remnant ablation with Thyrogen allows important management flexibility for physicians and treatment options for patients.”

The revised Prescribing Information (PI) for use of Thyrogen in ablation is based on the results of the two largest prospective studies ever conducted in thyroid cancer. The studies, published in the *New England Journal of Medicine* in May 2012, compared ablation success among patients receiving recombinant human thyrotropin (rhTSH) and patients undergoing thyroid hormone withdrawal (THW) at both low and high doses of radioiodine. In both studies, patients receiving Thyrogen rather than THW had fewer hypothyroid symptoms and preserved quality of life.

“The best path to achieve thyroid remnant ablation must be one that involves the least whole body radiation dose, the least early and late side-effects, the best quality of life, and the least healthcare costs, as demonstrated in these two landmark studies,” said Ujjal Mallick, M.D., Northern Centre for Cancer Care, Freeman Hospital, Newcastle UK.

Professor Martin Schlumberger, M.D., Institut Gustave Roussy, University Paris Sud, Paris, France, said, “The revised PI for Thyrogen provides a new option for many physicians who may be wanting to reduce radioiodine use due to uncertainty about impact of dosing on recurrences and mortality in low-risk patients as well as short- and long-term safety concerns.”

These findings have been reflected in the clinical studies section in the updated [Full Prescribing Information](#).

### **About Thyrogen**

Thyrogen<sup>®</sup> (thyrotropin alfa for injection) is for patients with well-differentiated thyroid cancer. Thyrogen is approved 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 distant metastatic thyroid cancer.

### **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).

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### **About Sanofi**

Sanofi, an integrated global 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).

### ***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 forwardlooking 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, 2013. 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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