

# Genzyme Provides Update on U.S. LEMTRADA™(\*) Filing

Paris, France - August 27, 2012 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced that Genzyme has received a Refuse to File letter from the U.S. Food and Drug Administration (FDA) in response to the supplemental Biologics License Application (sBLA) for the approval of LEMTRADA™ (alemtuzumab) as a treatment for relapsing multiple sclerosis.

After collaborative consultations with the FDA, the agency requested that the company modify the presentation of the data sets to enable the agency to better navigate the application. The FDA has not requested additional data or further studies. Genzyme will work with the FDA over the coming weeks to resubmit the application as soon as possible.

"We have had constructive dialogue with the FDA, and we are very confident in our ability to address the agency's request and resubmit rapidly", said David Meeker, President and CEO, Genzyme.

The company's marketing authorization application submitted to the European Medicines Agency has been accepted and the review process is underway.

Genzyme is developing LEMTRADA in MS in collaboration with Bayer HealthCare.

# **About Alemtuzumab/LEMTRADA™**

Alemtuzumab is a monoclonal antibody that selectively targets CD52, a protein abundant on T and B cells. Treatment with alemtuzumab results in the depletion of circulating T and B cells thought to be responsible for the damaging inflammatory process in MS. Alemtuzumab has minimal impact on other immune cells. The acute anti-inflammatory effect of alemtuzumab is immediately followed by the onset of a distinctive pattern of T and B cell repopulation that continues over time, rebalancing the immune system in a way that potentially reduces MS disease activity.

Genzyme holds the worldwide rights to alemtuzumab and has primary responsibility for its development and commercialization in multiple sclerosis. Bayer HealthCare retains an option to co-promote alemtuzumab in multiple sclerosis. Bayer HealthCare has notified Genzyme of its intention to co-promote under this option. Upon regulatory approval and commercialization, Bayer would receive contingent payments based on sales revenue.

(\*) Lemtrada<sup>TM</sup> is the proprietary name submitted to health authorities for the company's investigational multiple sclerosis agent alemtuzumab.

### 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.

## **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 Baver HealthCare**

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 17.2 billion (2011), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2011) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

#### 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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# **Contacts:**

**Sanofi Media Relations** 

Jean-Marc Podvin Tel: +33 (0) 1 53 77 46 46 E-mail: mr@sanofi.com

**Genzyme Media Relations** 

Erin Walsh

Tel: +1 617 768 6881

E-mail: <u>Erin.Walsh@genzyme.com</u>

**Sanofi Investor Relations** 

Sébastien Martel Tel: +33 (0) 1 53 77 45 45 E-mail: ir@sanofi.com

Sanofi US Investor Relations

George Grofik
Tel: +1 908 981 6031

E-mail: <u>ir@sanofi.com</u>