



Genzyme's LEMTRADA™ (alemtuzumab) Application for MS Accepted for Review by the FDA

-- Genzyme also Reports Very Encouraging Early Launch Indicators for AUBAGIO® (teriflunomide) in U.S. --

Paris, France -- January 28, 2013 – Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced that the U.S. Food and Drug Administration (FDA) has accepted for review the company's supplemental Biologics License Application (sBLA) file seeking approval of LEMTRADA™ (alemtuzumab) for the treatment of relapsing multiple sclerosis (RMS). The company also reported key highlights from the U.S. launch of once-daily, oral AUBAGIO (teriflunomide).

LEMTRADA sBLA Accepted by FDA

The FDA has accepted for standard review the company's sBLA file seeking approval of LEMTRADA. Genzyme expects FDA action on the application in the second half of 2013. Genzyme has already submitted its marketing authorization application for LEMTRADA to the European Medicines Agency (EMA) and the review process is underway. The Committee for Medicinal Products for Human Use (CHMP) opinion for LEMTRADA is expected in Q2 2013.

The LEMTRADA clinical development program includes CARE-MS I and CARE-MS II (Comparison of Alemtuzumab and Rebif® Efficacy in Multiple Sclerosis), randomized Phase III studies comparing LEMTRADA to a standard of care MS treatment, Rebif, in patients with relapsing-remitting MS who were naïve to prior treatment or who had relapsed while on prior therapy, respectively. Genzyme announced publication of results of these studies in *The Lancet* in November 2012.

AUBAGIO Early Launch Indicators in the U.S.

Since its launch in October, once-daily, oral AUBAGIO has shown very encouraging early launch indicators among U.S. prescribers.¹ Key highlights from the launch include:

- More than 80 percent of MS specialists in the U.S. have prescribed AUBAGIO;
- Approximately 1 in 5 patients prescribed AUBAGIO were treatment-naïve;
- More than 50 percent of AUBAGIO patients were most recently on Copaxone® and Avonex®

“Genzyme is making a difference for people living with MS and realizing its vision of being leaders in MS,” said Genzyme President and CEO, David Meeker, M.D. *“The initial uptake of AUBAGIO by U.S. prescribers shows the importance of a once-daily oral option in MS. In addition, the acceptance of the LEMTRADA file in the U.S. marks another important milestone in bringing this potentially transformative therapy to MS patients. We look forward to a series of product launches in 2013 in Europe and other major markets.”*

AUBAGIO is approved for use in both the U.S. and Australia.

¹ Based on data collected at Genzyme's MS One to One Patient and Provider Support Center, September 2012-January 2013.

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 is the proprietary name submitted to health authorities for the company's investigational multiple sclerosis agent alemtuzumab.

About AUBAGIO®

AUBAGIO is an immunomodulator with anti-inflammatory properties. Although the exact mechanism of action for AUBAGIO is not fully understood, it may involve a reduction in the number of activated lymphocytes in the central nervous system (CNS).

Indications and Usage

AUBAGIO (teriflunomide) is a once-daily, oral treatment indicated for patients with relapsing forms of multiple sclerosis (MS). AUBAGIO 14 mg has shown significant efficacy across key measures of MS disease activity, including reducing relapses, slowing the progression of physical disability, and reducing the number of brain lesions as detected by MRI.

Important Safety Information About AUBAGIO

The AUBAGIO label includes a boxed warning citing the risk of hepatotoxicity and, teratogenicity (based on animal data).

In MS clinical studies with AUBAGIO, the incidence of serious adverse events were similar among AUBAGIO and placebo-treated patients. The most common adverse events associated with AUBAGIO in MS patients included increased ALT levels, alopecia, diarrhea, influenza, nausea and paresthesia.

Teriflunomide is the principal active metabolite of leflunomide, which is indicated in the U.S. for the treatment of rheumatoid arthritis. Severe liver injury including fatal liver failure has been reported in patients treated with leflunomide.

Leflunomide has an estimated 2.1 million years of patient exposure in rheumatoid arthritis globally since its launch.

AUBAGIO is contraindicated in pregnant women and women of childbearing potential who are not using reliable contraception.

AUBAGIO is supported by a robust clinical program with more than 5,000 trial participants in 36 countries and is amongst the largest of any MS therapy. Some patients in extension trials have been treated for up to 10 years. The AUBAGIO approvals were based on efficacy data from the TEMSO (TEriflunomide Multiple Sclerosis Oral) trial.

For full prescribing information and more information about AUBAGIO, please visit www.genzyme.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. 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).

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About Bayer 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.

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.

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