



Genzyme Submits Applications to FDA and EMA for Approval of LEMTRADA™ (alemtuzumab) for Multiple Sclerosis

Paris, France - June 12, 2012 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme today announced that the company has submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) and a marketing authorization application (MAA) to the European Medicines Agency (EMA) seeking approval of LEMTRADA™ (alemtuzumab) for treatment of relapsing multiple sclerosis (RMS). Genzyme is developing LEMTRADA in MS in collaboration with Bayer HealthCare.

Genzyme's clinical development program for LEMTRADA included two Phase III studies in which results for LEMTRADA were superior to Rebif® (high dose subcutaneous interferon beta-1a) on clinical and imaging endpoints, including a reduction in relapse rate. In addition, as presented last month at the American Academy of Neurology meeting, some patients with pre-existing disability treated with LEMTRADA in the CARE-MS II trial were more than twice as likely to experience a sustained reduction in disability over two years than patients treated with Rebif.

"There remains a large unmet treatment need for patients living with active disease and we believe that LEMTRADA, given its efficacy and unique dosing schedule, has the potential to transform the lives of patients with Multiple Sclerosis," said David Meeker, M.D., President and Chief Executive Officer, Genzyme.

The regulatory submissions for LEMTRADA include two-year controlled efficacy and safety data from both treatment-naïve patients and those who relapsed while on therapy, with greater than five years of safety follow-up. Common adverse events associated with alemtuzumab were consistent across the Phase III program and included infusion-associated reactions and infections, which were generally mild to moderate in severity. Autoimmune adverse events were observed in some patients with cases being detected early through a monitoring program and managed using conventional therapies.

In addition to LEMTRADA, Genzyme's clinical development program for relapsing multiple sclerosis includes the once-daily oral treatment, AUBAGIO™ (teriflunomide), which is currently under review by the FDA and EMA.

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.



In both CARE-MS I and CARE-MS II trials, alemtuzumab 12 mg was given as an IV administration for a total of eight times over the course of the two-year study. The first treatment course of alemtuzumab was administered on five consecutive days, and the second course was administered on three consecutive days 12 months later. Rebif 44 mcg was administered by subcutaneous injection three times per week, each week, throughout the two years of study. In CARE-MS II, a third group of patients received alemtuzumab 24 mg (n=170), given on the same dosing schedule as the patients receiving alemtuzumab 12 mg (n=426).

Genzyme has the worldwide rights to alemtuzumab and has primary responsibility for its development and commercialization in MS. Bayer HealthCare has been co-developing alemtuzumab in MS with Genzyme. Bayer HealthCare retains an option to co-promote alemtuzumab in MS and, upon regulatory approval and commercialization, would receive contingent payments based on sales revenue.

*Lemtrada™ and Aubagio™ are the proprietary names submitted to health authorities for the company's investigational multiple sclerosis agent alemtuzumab and teriflunomide respectively.

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 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.

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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*Lemtrada[™] is the proprietary name submitted to health authorities for the company’s investigational multiple sclerosis agent alemtuzumab.

Rebif[®] is a registered trademark of EMD Serono, Inc. or affiliates.

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