



Genzyme Receives Positive CHMP Opinion for LEMTRADA™ (alemtuzumab) in Europe

*– CHMP also Recommends NAS Designation for AUBAGIO® (teriflunomide)
Following Positive Opinion on Approval in March 2013 –*

*– Positive Opinions Set Stage for Introduction
of Two New Genzyme Therapies for Multiple Sclerosis in Europe –*

Paris, France – June 28, 2013 – Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion for approval of LEMTRADA™ (alemtuzumab) for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.

In addition, the CHMP issued a positive opinion on new active substance designation (NAS) for AUBAGIO® (teriflunomide). Earlier this year, the CHMP issued a positive opinion recommending the approval of AUBAGIO for the treatment of adult patients with relapsing remitting MS.

The European Commission (EC) is expected to render a final decision to grant marketing authorizations for LEMTRADA and AUBAGIO in the EU in the coming months.

“Today’s CHMP opinions set the stage for the approval of two important new treatment options for MS patients. Treatments to-date have addressed some of the unmet needs in MS, but still have limitations,” said David Meeker, MD, Genzyme President and CEO. *“Upon approval, physicians will have the ability to prescribe LEMTRADA for appropriate relapsing remitting patients based on their impressions of clinical or imaging characteristics regardless of duration of disease or treatment history. Expectations among the MS community are high for LEMTRADA and with today’s positive CHMP opinion we are a step closer to making this very innovative treatment available for MS patients in Europe.”*

The positive CHMP opinion for approval of LEMTRADA was based on data from the CARE-MS I and CARE-MS II trials, in which LEMTRADA was significantly more effective than Rebif® (subcutaneous interferon beta-1a 44 mcg three times weekly) at reducing relapse rates. In CARE-MS II, accumulation of disability was significantly slowed in patients given LEMTRADA vs. Rebif, and importantly, patients treated with LEMTRADA were significantly more likely to experience improvement in pre-existing disability.

“Today’s announcement from Genzyme represents a key milestone in the extensive program evaluating LEMTRADA in multiple sclerosis,” said Professor Alastair Compston, Head of the Department of Clinical Neurosciences at the University of Cambridge, United Kingdom. *“The superior efficacy of Lemtrada vs. Rebif in the clinical trials, which was sustained despite infrequent administration, represents an approach to treatment that promises to reshape the future for many people with active relapsing-remitting multiple sclerosis.”*

LEMTRADA has a novel dosing and administration schedule of two annual treatment courses. The first treatment course of LEMTRADA is administered via intravenous infusion on five consecutive days, and the second course is administered on three consecutive days, 12 months later.

The LEMTRADA clinical development program included two randomized Phase III studies comparing treatment with LEMTRADA to Rebif in patients with relapsing-remitting MS who had active disease and were either new to treatment (CARE-MS I) or who had relapsed while on prior therapy (CARE-MS II), as well as an ongoing extension study. A large randomized Phase II study provided the foundation for the Phase III program.

Safety results were consistent across both the CARE-MS I and CARE-MS II studies. The most common adverse events associated with LEMTRADA were infusion-associated reactions, including headache, rash, fever, nausea and hives. Infections were common in both the LEMTRADA and Rebif groups. Infections more common on LEMTRADA treatment included upper respiratory and urinary tract infections, herpes viral infections, and influenza. Most infusion-associated reactions and infections were mild to moderate in severity and responded to standard treatments.

In both CARE-MS I and CARE-MS II, the incidence of serious adverse events was similar between the two treatment arms. As previously reported, autoimmune disorders were more frequent in patients treated with LEMTRADA, primarily autoimmune thyroid disease which was observed in an estimated 36% of patients during extended follow-up. Immune thrombocytopenia (ITP) developed in 1.4 percent of LEMTRADA-treated patients through extended follow-up and 0.3% developed glomerulonephritis. Autoimmune disorders were detected soon after onset through a monitoring program, and were generally managed using standard treatments.

A comprehensive risk management program has been proposed to support early detection and management of adverse events.

In the U.S. the 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). FDA recently extended the review cycle for LEMTRADA™ by three months; no additional clinical studies have been requested, therefore FDA action on the application is expected in late 2013.

About LEMTRADA™ (alemtuzumab)

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® (teriflunomide)

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).

U.S. Indications and Usage

AUBAGIO (teriflunomide) is a once-daily, oral treatment indicated in the U.S. 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. AUBAGIO 7mg has shown significant efficacy in reducing relapses and reducing the number of brain lesions as detected by MRI.

Important Safety Information About AUBAGIO

The AUBAGIO U.S. 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. and Europe 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 patient years of 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 EU AUBAGIO submission includes efficacy data from the TOWER (T_{eriflunomide} O_{ral} in people With relapsing remitting multiple E sclerRosis) and TEMSO (T_{eriflunomide} M_{ultiple} S_{cler}osis O_{ral}) trials.

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.

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

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).

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 18.6 billion (2012), 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 55,300 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.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, 2012. 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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