Genzyme's Lemtrada Approved by the FDA

- Approval Establishes Genzyme's MS Franchise in the U.S. with Two Approved Products; Follows Global Approvals -

Paris - November 15, 2014 - Sanofi and its subsidiary Genzyme announced today that the U.S. Food and Drug Administration (FDA) has approved Lemtrada™ (alemtuzumab) for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

"*Today's approval is the culmination of more than a decade of work by Genzyme to develop Lemtrada*," said Genzyme President and CEO, David Meeker. *"Lemtrada demonstrated superior efficacy over Rebif on annualized relapse rates in the two studies which were the basis for approval. A comprehensive risk evaluation and mitigation strategy (REMS) will be instituted in order to help detect and manage the serious risks identified with treatment."*

The FDA approval of Lemtrada is based on two pivotal randomized Phase III open-label rater-blinded studies comparing treatment with Lemtrada to Rebif® (high-dose subcutaneous interferon beta-1a) in patients with relapsing remitting MS who were either new to treatment (CARE-MS I) or who had relapsed while on prior therapy (CARE-MS II).

In CARE-MS I, Lemtrada was significantly more effective than interferon beta-1a at reducing annualized relapse rates; the difference observed in slowing disability progression did not reach statistical significance. In CARE-MS II, Lemtrada was significantly more effective than interferon beta-1a at reducing annualized relapse rates, and accumulation of disability was significantly slowed in patients given Lemtrada vs. interferon beta-1a. The clinical development program for Lemtrada involved nearly 1,500 patients with more than 6,400 patient-years of safety follow-up.

"The unmet need in MS remains high," said Edward Fox, M.D., Ph.D., Director of the Multiple Sclerosis Clinic of Central Texas. "*It is a great day for people living with relapsing forms of MS in the United States, who will now have access to this new meaningful treatment".*

The Lemtrada label includes a boxed warning noting a risk of serious, sometimes fatal autoimmune conditions, serious and life-threatening infusion reactions and also noting Lemtrada may cause an increased risk of malignancies including thyroid cancer, melanoma and lymphoproliferative disorders.

Lemtrada is only available through a restricted distribution program, the Lemtrada REMS (Risk Evaluation and Mitigation Strategy). This program has been developed to ensure that access to Lemtrada in the U.S. is only through certified prescribers, healthcare facilities and specialty pharmacies and to also ensure that patients are enrolled in the REMS program. The program is intended to help educate healthcare providers and patients on the serious risks associated with Lemtrada and the appropriate periodic monitoring required to support the detection of these risks for 48 months after the last infusion. The REMS is based on a developmental risk management program that was successfully implemented in the Phase 2 and Phase 3 trials and allowed for early detection and management of some of the serious risks associated with Lemtrada.

"*The FDA approval of Lemtrada is a significant milestone for people living with relapsing MS in the United States*," said Dr. Timothy Coetzee, Chief Advocacy, Services and Research Officer at the National MS Society. "*We are pleased that the voices of the MS community have been recognized and that people with relapsing MS will now have access to a new, needed treatment option*."

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

The most common side effects of Lemtrada are rash, headache, pyrexia, nasopharyngitis, nausea, urinary tract infection, fatigue, insomnia, upper respiratory tract infection, herpes viral infection, urticaria, pruritus, thyroid gland disorders, fungal infection, arthralgia, pain in extremity, back pain, diarrhea, sinusitis, oropharyngeal pain, paresthesia, dizziness, abdominal pain, flushing, and vomiting. Other serious side effects associated with Lemtrada include autoimmune thyroid disease, autoimmune cytopenias, infections and pneumonitis.

First approved in September 2013 in the European Union, Lemtrada is approved in more than 40 countries. Additional marketing applications for Lemtrada are under review by regulatory agencies around the world.

The FDA approval of Lemtrada marks Genzyme's second MS treatment approval in the United States. Genzyme received FDA approval of its once-daily, oral Aubagio® (teriflunomide) for the treatment of relapsing forms of MS in September 2012. Aubagio is approved in more than 50 countries, and is under review by additional regulatory agencies. Between clinical trials and commercial use, approximately 30,000 patients have been treated with Aubagio.

Multiple sclerosis is estimated to affect more than 2.3 million people globally. There are approximately 400,000 people living with MS in the United States.

Important Safety Information About Lemtrada for U.S. Patients

Serious and life-threatening autoimmune conditions such as immune thrombocytopenia (ITP) and anti-glomerular basement membrane disease can occur in patients receiving Lemtrada. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals in patients who receive Lemtrada. Lemtrada is associated with serious and life-threatening infusion reactions. Lemtrada can only be administered in certified healthcare settings that have on-site access to equipment and personnel trained to manage anaphylaxis and serious infusion reactions. Lemtrada may be associated with an increased risk of malignancy, including thyroid cancer, melanoma and lymphoproliferative disorders. The Lemtrada REMS Program, a comprehensive risk management program with frequent monitoring, is being implemented to help mitigate these serious risks.

The Lemtrada label includes a boxed warning noting a risk of serious, sometimes fatal autoimmune conditions, serious and life-threatening infusion reactions and also noting Lemtrada may cause an increased risk of malignancies including thyroid cancer, melanoma and lymphoproliferative disorders. Lemtrada is contraindicated in patients with Human Immunodeficiency Virus (HIV) infection.

U.S. Indication and Usage

Lemtrada is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Please click **here** for full U.S. Prescribing Information for Lemtrada, including boxed warning and contraindications.

As part of its continued commitment to MS patients, Genzyme's *MS One to One*® program will provide information about multiple sclerosis, Lemtrada and other relevant resources. *MS One to One* is available and staffed by dedicated MS nurses and highly trained representatives who can provide support for individuals living with MS, their health care providers, family and loved ones. For more information about these support services, call the *MS One to One* line at 1-855-MSOne2One (1-855-676-6326) Monday through Friday, from 8:30am – 8:00pm ET. Information and support are also available at www.MSOnetoOne.com

About Lemtrada™ (alemtuzumab)

Alemtuzumab is a monoclonal antibody that targets CD52, a protein abundant on T and B cells. Circulating T and B cells are thought to be responsible for the damaging inflammatory process in MS. Alemtuzumab depletes circulating T and B lymphocytes after each treatment course. Lymphocyte counts then increase over time with a reconstitution of the lymphocyte population that varies for the different lymphocyte subtypes.

In CARE-MS I, Lemtrada was significantly more effective than interferon beta-1a at reducing annualized relapse rate (0.18 for Lemtrada and 0.39 for interferon beta-1a ($p<0.0001$) a 55 percent relative reduction. The difference observed in proportion of patients with disability progression at year two did not reach statistical significance (8 percent for Lemtrada and 11 percent for interferon beta 1-a ($p=0.22$)), a relative risk reduction of 30 percent. The percent of patients remaining relapse-free at year two for Lemtrada was 78 percent vs. 59 percent for interferon beta-1a ($p<0.0001$). The percent change in T2 lesion volume from baseline did not reach statistical significance (-9.3 for Lemtrada and -6.5 for interferon beta 1-a, $p=0.31$).

In CARE-MS II, Lemtrada was significantly more effective than interferon beta-1a at reducing annualized relapse rates (0.26 for Lemtrada and 0.52 for interferon beta 1-a, $p<0.0001$, a 49 percent relative reduction). The proportion of patients with confirmed six-month disability progression was significantly lower for Lemtrada (13 percent for Lemtrada vs. 21 percent for interferon beta 1-a, $p=0.0084$), a 42 percent relative risk reduction. The percent of patients remaining relapse-free at year two for Lemtrada was 65 percent vs. 47 percent for interferon beta-1a ($p<0.0001$). The percent change in T2 lesion volume from baseline did not reach statistical significance (-1.3 for Lemtrada and -1.2 for interferon beta 1-a, $p=0.14$).

Genzyme holds the worldwide rights to alemtuzumab and has responsibility for its development and commercialization in multiple sclerosis. Bayer Healthcare receives contingent payments based on global sales revenue.

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). Aubagio is supported by one of the largest clinical programs of any MS therapy, with more than 5,000 trial participants in 36 countries. Some patients in extension trials have been treated for up to 10 years.

U.S. Indication and Usage

Aubagio (teriflunomide) is a once-daily, oral therapy indicated for the treatment of adult patients with relapsing forms of multiple sclerosis. The recommended dose of Aubagio is 7 mg or 14 mg orally once-daily.

Important Safety Information About Aubagio for U.S. Patients

The Aubagio label includes the risk of hepatotoxicity and, teratogenicity (based on animal data). In the United States, this information can be found in the boxed warning.

In MS clinical studies with Aubagio, the incidence of serious adverse events were similar among Aubagio and placebo-treated patients. Serious events may include decreased white blood cell count, peripheral neuropathy, hyperkalemia, skin reactions and increased blood pressure. 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. ALT should be monitored monthly for at least 6 months in patients who start treatment with Aubagio.

Aubagio is contraindicated in patients with severe hepatic impairment, pregnant women and women of childbearing potential who are not using reliable contraception and in patients who are taking leflunomide. Aubagio is not recommended for breast-feeding women, patients with immunodeficiency states, patients with significantly impaired bone marrow function or significant anemia, leucopenia, neutropenia or thrombocytopenia, patients with severe active infection until resolution, patients with severe renal impairment undergoing dialysis and patients with hypoproteinaemia.

Please click here for full U.S. Prescribing Information for Aubagio, including boxed warning and contraindications.

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 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 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, 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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