Effect of Genzyme's Multiple Sclerosis Treatment Lemtrada® (alemtuzumab) on Slowing Brain Atrophy and MRI Lesion Activity Maintained Through Four Years

- Approximately 70% of Lemtrada Patients Had Not Received Any Additional Lemtrada Treatment in the Prior Three Years -

Paris - April 23, 2015 - Sanofi and its subsidiary Genzyme announced that new magnetic resonance imaging (MRI) data from the Lemtrada® (alemtuzumab) clinical development program will be presented today at the 67th American Academy of Neurology (AAN) Annual Meeting.

In relapsing remitting multiple sclerosis (RRMS) patients treated with Lemtrada in the Phase III pivotal studies, MRI effects observed in the two-year trials were maintained through two additional years in the extension study (years three and four). After the initial two courses of treatment in the pivotal studies, which were given at month zero and at month 12, approximately 70 percent of Lemtrada patients did not receive additional Lemtrada treatment during the following three years, through month 48.

The Phase III trials of Lemtrada were randomized, two-year pivotal studies comparing treatment with Lemtrada to high-dose subcutaneous interferon beta-1a (Rebif®) in patients with RRMS who had active disease and were either new to treatment (CARE-MS I) or who had an inadequate response to another therapy (CARE-MS II).

Through year four, the adverse event profile of Lemtrada was consistent with that observed during the pivotal studies. The new data being presented at AAN include:

- The rate of brain atrophy, as measured by brain parenchymal fraction (BPF), decreased progressively over four years among Lemtrada patients in CARE-MS I. Among CARE-MS II Lemtrada patients, the rate of brain atrophy decreased progressively over three years and remained low in year four. In both studies, the median yearly brain volume loss was less than -0.20% in years three and four, which was lower than what was observed during the two-year pivotal studies.

- In CARE-MS I and II, treatment with Lemtrada significantly reduced the risk of developing new lesions compared to interferon beta-1a. In the extension study, most of the Lemtrada-treated patients from CARE-MS I and II were free of new lesions and MRI activity in years three and four (approximately 70%).

Brain atrophy is a measure of the most destructive pathological processes that occur in MS.[1] It is seen from the earliest stages of disease and may lead to irreversible neurological and cognitive impairment. Given its association with disability, control or prevention of brain atrophy is an important target for MS treatment. In addition, MRI measures including lesion activity are considered useful tools when evaluating the effect of MS therapies, and lesion activity is among several prognostic factors for unfavorable clinical outcomes.[2]

"It is very promising that most Lemtrada patients experienced slowing of brain atrophy and remained free of new lesions despite receiving their last treatment course three years previously," said Dr.

Alasdair Coles, Professor, Department of Clinical Neurosciences, University of Cambridge. *"These new MRI data are consistent with the clinical data from the extension study that provide additional evidence of the sustained efficacy of Lemtrada on both relapses and disability."*

Safety results from the second year of the extension study were previously reported. No new risks were identified. 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. A risk management program incorporating education and monitoring helps support early detection and management of these identified risks (see Important Safety Information About Lemtrada for U.S. Patients below).

"*The four-year MRI data support the prolonged efficacy of Lemtrada,*" said Genzyme President and CEO, David Meeker, M.D. "*These results are encouraging, as they provide further evidence of Lemtrada's potential to change the treatment approach for people living with relapsing forms of MS*."

More than 90 percent of the patients who were treated with Lemtrada in the CARE-MS Phase III trials enrolled in the extension study. These patients were eligible to receive additional treatment with Lemtrada in the extension study if they experienced at least one relapse or at least two new or enlarging brain or spinal cord lesions. MRI scans were taken at CARE-MS baseline, and at 12, 24, 36 and 48 months.

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.

Lemtrada® (alemtuzumab) U.S. Indication and Usage

Lemtrada is indicated in the United States 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. Lemtrada is contraindicated in patients who are infected with Human Immunodeficiency Virus (HIV) because Lemtrada causes prolonged reductions of CD4+ lymphocyte counts.

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

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 risk management program with frequent monitoring, has been 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.

About Lemtrada® (alemtuzumab)

Lemtrada is approved in more than 40 countries, with additional marketing applications under review. Lemtrada is supported by a comprehensive and extensive clinical development program that involved nearly 1,500 patients and 5,400 patient-years of follow-up.

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. Although the exact mechanism of action for alemtuzumab is unknown, it is presumed to deplete 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.

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 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).

References

(1) American Journal of Neuroradiology, August 2014 http://ajnrdigest.org/brain-atrophy-multiple-sclerosis/
(2) Cleveland Clinic, Center For Continuing Education, Medical Publications, Multiple Sclerosis, June 2014 http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/neurology/multiple_sclerosis/

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, 2014. 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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