



At Four Years, Treatment Effect Maintained in More Than Two-Thirds of Patients Who Received Genzyme's Lemtrada in Pivotal Studies

- In approximately 70 percent of patients, disability scores improved or remained stable for an additional two years beyond the two-year pivotal multiple sclerosis studies -

- Approximately 70 percent of patients treated with Lemtrada did not receive a third course of treatment through the second year of the extension -

Paris – September 11, 2014 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today positive interim results from the second year of the extension study of Lemtrada™ (alemtuzumab) for multiple sclerosis.

In this analysis, relapse rates and sustained accumulation of disability remained low among patients who had previously received Lemtrada in either of the Phase III CARE-MS I and CARE-MS II studies. In these pivotal studies, Lemtrada was given as two annual courses, at the start of the study and 12 months later. Approximately 70 percent of patients who received Lemtrada in the pivotal studies did not receive further treatment with Lemtrada through the second year of the extension study. No new safety signals were identified. These data will be presented today at the European Committee for Research and Treatment in Multiple Sclerosis (ECTRIMS) meeting in Boston.

"These extension study results provide further evidence of the prolonged efficacy of Lemtrada on both relapses and disability," said Dr. Alasdair Coles, Senior Lecturer, Department of Clinical Neurosciences, University of Cambridge. *"The majority of patients continued to experience reduced disease activity, even though their last Lemtrada treatment was three years earlier."*

Extension Study Results

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 relapsing-remitting multiple sclerosis who had active disease and were either new to treatment (CARE-MS I) or who had relapsed while on prior therapy (CARE-MS II).

More than 90 percent of the patients who were treated with Lemtrada in the 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.

The following interim results are from the second year of the extension study for patients who previously received Lemtrada in the two-year pivotal studies:

- In year four, the annualized relapse rates for patients who received Lemtrada in CARE-MS I and CARE-MS II were 0.14 and 0.23, respectively. These rates were comparable to the annualized relapse rates for those patients who received Lemtrada in the pivotal trials.
- Through year four, 74 percent of patients in CARE-MS I and 66 percent in CARE-MS II had improved or stable disability as measured by the Expanded Disability Status Scale (EDSS).

- Through year four, 83 percent and 76 percent of patients who received Lemtrada in the pivotal trials, respectively, did not experience six-month sustained accumulation of disability – meaning they did not experience a worsening of their disability that persisted for six continuous months in the four years of observation.
- Approximately 70 percent of patients treated with Lemtrada in the pivotal studies did not receive a third course of treatment in years three and four.

“MS is a devastating disease and patients remain in need of new treatment options that may offer greater efficacy. These new data reinforce the transformative potential of Lemtrada,” said Genzyme President and CEO, David Meeker, M.D. *“It is encouraging to see the durable efficacy and manageable safety of Lemtrada maintained two years into the extension study.”*

Safety results from the second year of the extension study were reported. No new risks were identified. As previously reported, there were two deaths in the extension study. One was from sepsis and the other was presumed accidental and deemed unrelated to study treatment. Over four years, approximately 2 percent of patients treated with Lemtrada in the pivotal trials developed immune thrombocytopenia (ITP), all of whom responded to treatment. Patient monitoring for autoimmune disorders is incorporated in all Genzyme-sponsored trials of Lemtrada.

The most common side effects of Lemtrada are infusion associated reactions (headache, rash, pyrexia, nausea, fatigue, urticaria, insomnia, pruritus, diarrhea, chills, dizziness, and flushing), infections (upper respiratory tract and urinary tract), and thyroid disorders. Autoimmune conditions (including immune thrombocytopenia, other cytopenias, glomerulonephritis and thyroid disease) and serious infections can occur in patients receiving Lemtrada. A comprehensive risk management program incorporating education and monitoring will help support early detection and management of these identified risks.

About CARE-MS

The Lemtrada clinical development program included two randomized Phase III 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 relapsed while on prior therapy (CARE-MS II), as well as an ongoing extension study. 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.

About Lemtrada™ (alemtuzumab)

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. Lemtrada 12 mg has a novel 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.

Lemtrada is approved in the European Union, Australia, Canada, Mexico, Brazil, Argentina, Chile and Guatemala. Lemtrada is currently not approved in the United States. The U.S. Food and Drug Administration (FDA) has accepted for review the company’s resubmission of its application seeking approval of Lemtrada, and Genzyme expects FDA action on the application in the fourth quarter. Marketing applications for Lemtrada are also under review in other countries.

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 holds the right to co-promote alemtuzumab in MS in the United States. Upon commercialization, Bayer will receive 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.

Genzyme[®] is a registered trademark and Lemtrada[™] is a trademark of Genzyme Corporation. Rebif[®] is a registered trademark of EMD Serono, Inc.

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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