

# Genzyme's Lemtrada<sup>®</sup> Approved in Mexico for Treatment of Multiple Sclerosis

**Cambridge, Mass. – February 4, 2014 –** Genzyme, a Sanofi company (EURONEXT: SAN and NYSE: SNY), announced today that Mexico's national regulatory authority, COFEPRIS, has approved Lemtrada (alemtuzumab) for the treatment of patients with relapsing remitting forms of multiple sclerosis (MS) to slow or reverse the accumulation of physical disability and reduce the frequency of clinical exacerbations.

"The approval of Lemtrada in Mexico is an important step forward for MS patients, who remain in great need of new treatment options that may offer greater efficacy," said Miguel A. Macias, M.D., Department of Neuroscience, University of Guadalajara. "The positive effect on disability progression demonstrated in clinical studies underscores Lemtrada's ability to address the course of disease in a potentially transformative way for patients with relapsing remitting MS."

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. Approval in Mexico follows the recent approvals of Lemtrada in Canada, Australia and the European Union. Lemtrada is currently not approved in the United States. In December, Genzyme received a complete response letter from the FDA on its application for U.S. approval of Lemtrada. Genzyme plans to appeal the agency's decision. Marketing applications for Lemtrada are also under review in other countries.

More than 2.3 million people worldwide have been diagnosed with MS, including approximately 15,000 people in Mexico. Lemtrada has been granted orphan drug designation in Mexico.

Lemtrada 12 mg 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 approvals in the European Union, Australia, Canada and now Mexico underscore Lemtrada's potential to have a positive impact on the lives of MS patients," said Genzyme President and CEO, David Meeker. "Genzyme remains committed to providing new hope for the MS community and plans this year to launch Lemtrada in more than 30 countries, and hopefully additional markets where the treatment is still under review."

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.

The most common side effects of Lemtrada are infusion associated reactions, infections (upper respiratory tract and urinary tract), lymphopenia and leukopenia. Autoimmune conditions and serious infections can occur in patients receiving Lemtrada. A comprehensive risk management program

incorporating education and monitoring will support early detection and management of these identified risks.

## 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 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<sup>®</sup> and Lemtrada<sup>®</sup> are registered trademarks of Genzyme Corporation. Rebif<sup>®</sup> is a registered trademark of EMD Serono, Inc.

### **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).

#### 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 forwardlooking 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 labeling 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.

### **Contacts:**

**Genzyme Media Relations** 

Erin Walsh

Tel: + 1 617 768 6881

E-mail: <a href="mailto:erin.walsh@genzyme.com">erin.walsh@genzyme.com</a>

**Sanofi Investor Relations** 

Kristen Galfetti

Tel: +1 908 981 5560 E-mail: <u>ir@sanofi.com</u>