



Genzyme Receives Complete Response Letter from FDA on Lemtrada™ (alemtuzumab) Application

Paris, France - December 30, 2013 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today that it has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for its supplemental Biologics License Application seeking approval of Lemtrada (alemtuzumab) for the treatment of relapsing forms of multiple sclerosis.

A Complete Response Letter informs companies that an application is not ready for approval. FDA has taken the position that Genzyme has not submitted evidence from adequate and well-controlled studies that demonstrate the benefits of Lemtrada outweigh its serious adverse effects. Genzyme understands that the conclusion is related to the design of the completed Phase 3 active comparator studies of Lemtrada in relapsing-remitting MS patients. FDA has also taken the position that one or more additional active comparator clinical trials of different design and execution are needed prior to the approval of Lemtrada.

Genzyme strongly disagrees with the FDA's conclusions and plans to appeal the agency's decision.

"We are extremely disappointed with the outcome of the review and the implications for patients in the U.S. suffering with multiple sclerosis who remain in need of alternative therapies to manage a devastating disease," said Genzyme President and CEO, David Meeker, M.D. "We strongly believe that the clinical development program, which was designed to demonstrate how Lemtrada compares against an active comparator as opposed to placebo, provides robust evidence of efficacy and a favorable risk-benefit profile. This evidence was also the basis for the approvals of Lemtrada by other regulatory agencies around the world."

Lemtrada is approved in the European Union, Canada, and Australia, and additional marketing applications for Lemtrada are under review by regulatory agencies around the world.

Sanofi does not anticipate that the CVR milestone of U.S. approval of Lemtrada by March 31, 2014 will be met.

About Lemtrada™ (alemtuzumab)

The Lemtrada clinical development program included two pivotal randomized Phase III studies comparing treatment with Lemtrada to Rebif® (high-dose subcutaneous interferon beta-1a) 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 Rebif 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. Serious autoimmune conditions can occur in patients receiving Lemtrada. A comprehensive risk management program will support early detection and management of these autoimmune events.

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.

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).

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

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 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:

Sanofi Media Relations

Jack Cox

Tel: +33 (0) 1 53 77 46 46

E-mail: mr@sanofi.com

Genzyme Media Relations

Erin Pascal

Tel: + 1 857 248 0874

E-mail: Erin.Pascal@genzyme.com

Sanofi Investor Relations

Sébastien Martel

Tel: +33 (0) 1 53 77 45 45

E-mail: ir@sanofi.com

Sanofi Investor Relations

Kristen Galfetti

Tel: +1 908 981 5560

E-mail: ir@sanofi.com