



## Genzyme Demonstrates Depth of MS Pipeline at AAN with Results from Multiple Sclerosis Phase III Trials

### - Full CARE-MS II Results for Alemtuzumab to Be Unveiled -

Paris, France - April 20, 2012 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today that 12 data presentations, including six platform presentations, from the company's multiple sclerosis (MS) clinical trial programs for alemtuzumab and teriflunomide will be featured at the *American Academy of Neurology's* (AAN) 64<sup>th</sup> Annual Meeting in New Orleans, La., April 21-28. Presentations will include full data results from CARE-MS II (The Comparison of alemtuzumab and Rebif<sup>®</sup> Efficacy in Multiple Sclerosis), a Phase III trial investigating alemtuzumab in MS patients who had relapsed while receiving prior MS therapy, as well as new findings from the teriflunomide clinical program, one of the largest and broadest of any MS therapy in development.

*"Genzyme's robust development programs for alemtuzumab and teriflunomide were designed to understand how these therapies can best address significant unmet medical needs of people living with MS,"* said David Meeker, M.D., President and CEO, Genzyme. *"We are committed to becoming a long-term partner to the MS community with the goal of raising the expectation of what life with MS can be."*

Marketing applications for teriflunomide for the treatment of relapsing forms of MS are under review by the U.S. Food & Drug Administration (FDA) and European Medicines Agency (EMA). Genzyme is on track to submit applications to the FDA and EMA for approval of alemtuzumab to treat relapsing forms of MS in the second quarter of this year.

Following are selected scientific abstracts highlighting new results from the Phase III CARE-MS II and CARE-MS I trials for alemtuzumab, as well as the Phase III TEMSO (Study of Teriflunomide in Reducing the Frequency of Relapses and Accumulation of Disability in Patients With Multiple Sclerosis) trial for teriflunomide.

#### **ALEMTUZUMAB CARE-MS II Platform Presentation:**

- Efficacy and Safety Results From Comparison of Alemtuzumab and Rebif Efficacy in Multiple Sclerosis II (CARE-MS II): A Phase III Study in Relapsing-Remitting Multiple Sclerosis Patients Who Relapsed on Prior Therapy (Platform Presentation S01.004; April 24; 1:45 p.m. CT, 2:45 p.m. ET)

#### **ALEMTUZUMAB CARE-MS I Platform Presentations:**

- Efficacy and Safety Results From Comparison of Alemtuzumab and Rebif Efficacy in Multiple Sclerosis I (CARE-MS I): A Phase III Study in Relapsing-Remitting Treatment-Naïve Patients (Platform Presentation S01.006; April 24; 2:15 p.m. CT, 3:15 p.m. ET)
- Effect of Alemtuzumab vs. Rebif on Brain MRI Measurements: Results of CARE-MS I, a Phase III Study (Platform Presentation S11.006; April 24; 4:15 p.m. CT, 5:15 p.m. ET)
- Incidence of Autoimmunity in a Phase III Trial: Comparison of Alemtuzumab and Rebif in Multiple Sclerosis I (CARE-MS I) (Platform Presentation S41.006; April 26; 2:15 p.m. CT, 3:15 p.m. ET)
- Infections in Phase III Study: Comparison of Alemtuzumab and Rebif Efficacy in Multiple Sclerosis I (CARE-MS I) (Platform Presentation S41.007; April 26; 2:30 p.m. CT, 3:30 p.m. ET)



### **TERIFLUNOMIDE TEMSO Platform Presentation:**

- Effect of Teriflunomide on Relapses With Sequelae and Relapse Leading to Hospitalization in a Population With Relapsing Forms of Multiple Sclerosis: Results From the TEMSO Study (Platform Presentation S30.003; April 25; 2:30 p.m. CT, 3:30 p.m. ET)

Additional Genzyme MS portfolio data to be presented include:

### **ALEMTUZUMAB:**

- Relapse Outcomes With Alemtuzumab vs. Rebif in Treatment-Naïve Relapsing-Remitting Multiple Sclerosis (CARE-MS I): Secondary and Tertiary Endpoints (Poster Discussion PD5.004; April 25; 2:00 p.m. CT, 3:00 p.m. ET)
- Activity of an Anti-Murine CD52 Antibody in Experimental Autoimmune Encephalomyelitis (Poster P05.117; April 25; 2:00 p.m. CT, 3:00 p.m. ET)

### **TERIFLUNOMIDE:**

- Effect of Repeated Doses of Teriflunomide on a Single Oral Dose of Bupropion in Healthy Male Subjects (Poster P04.143; April 25; 7:30 a.m. CT, 8:30 a.m. ET)
- Teriflunomide Increases the Proportion of Patients Free From Disease Activity in the TEMSO Phase III Study (Poster Discussion PD5.007; April 25; 2:00 p.m. CT, 3:00 p.m. ET)
- Pregnancy Outcomes From the Teriflunomide Clinical Development Program: Retrospective Analysis of a Global Pharmacovigilance Database (Poster P06.190; April 26; 7:30 a.m. CT, 8:30 a.m. ET)
- Impact of Relapses With Sequelae on Disability, Health-Related Quality of Life, and Fatigue in a Population With Relapsing Forms of Multiple Sclerosis Using Data From TEMSO, a Pivotal Phase III Teriflunomide Trial (Poster P07.082; April 26; 2:00 p.m. CT, 3:00 p.m. ET)

###

**Sanofi will host a conference call for the financial community during the upcoming American Academy of Neurology Annual Meeting, including the results of the CARE - MS II study.**

It will take place on Wednesday 25th April, 2012 at:  
15:00 Paris CEST / 14:00 London BST/ 9.00 New York EDT

The conference call will include a presentation followed by a Q&A session.  
It will be accessible through audio webcast at [www.sanofi.com](http://www.sanofi.com)  
and via the following telephone numbers.

#### **CALL IN NUMBERS**

France +33 (0) 1 70 77 09 38  
UK +44 (0) 203 367 9457  
USA +1 866 907 5925

#### **AUDIO REPLAY**

An audio replay of the call will be available through the numbers below.  
The replay will be available approximately 2 hours after the end of the call.

France +33 (0) 1 72 00 15 00  
UK +44 (0) 203 367 9460  
USA +1 877 642 3018  
Access code 276606#

###



### **About 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. Although the exact mechanism of effect in MS is unknown, this repopulation creates a re-balanced immune system that potentially reduces MS disease activity.

In addition to the completed CARE-MS II study, another Phase III trial, CARE-MS I, evaluated alemtuzumab against Rebif (interferon beta-1a) in relapsing-remitting MS patients naive to prior treatment and found a statistically significant reduction in relapse rate with alemtuzumab. In both trials, alemtuzumab 12 mg was given as an IV administration on eight days over the course of the two-year study. The first treatment course of alemtuzumab was administered on five consecutive days, and the second course was administered on three consecutive days 12 months later. Rebif 44 mcg was administered by subcutaneous injection three times per week, each week, throughout the two years of study.

Genzyme has the worldwide rights to alemtuzumab and has primary responsibility for the development and commercialization in MS. Bayer HealthCare has been co-developing alemtuzumab in MS with Genzyme. Bayer HealthCare retains an option to co-promote alemtuzumab in MS and upon regulatory approval and commercialization would receive contingent payments based on sales revenue.

### **About Teriflunomide**

Teriflunomide, a once daily oral tablet, is an immunomodulator with a unique mechanism of action. Although the mechanism of action for teriflunomide is not fully understood, research supports that teriflunomide inhibits the proliferation of stimulated T and B lymphocytes in the periphery thought to be responsible for the damaging inflammatory process in MS, while generally maintaining normal immune function. Teriflunomide selectively and reversibly inhibits DHODH, a key enzyme in de novo pyrimidine synthesis required by rapidly dividing lymphocytes. Through this effect, it limits the expansion of stimulated T- and B-cells in the periphery and diminishes the numbers of activated T- and B-cells available to migrate into the central nervous system (CNS). Because the salvage pathway for pyrimidine synthesis is not affected by teriflunomide, resting lymphocytes maintain their viability and remain unaffected by teriflunomide.

Teriflunomide is being studied in a large clinical program that is expected to include more than 5,000 trial participants in 36 countries. Six efficacy clinical trials are either completed or underway with teriflunomide, making the clinical program one of the largest of any MS agent under development. In addition to the completed TEMSO and TENERE trials, the Phase III, placebo-controlled trial TOWER was recently completed in people with relapsing forms of MS. Another Phase III study, TOPIC, is underway in early MS or CIS (clinically isolated syndrome). Teriflunomide is also being evaluated as an adjunctive therapy to interferon- $\beta$  in the Phase III TERACLES trial. With up to 10 years of continuous use in a Phase II extension, teriflunomide has the longest clinical experience of any investigational oral MS therapy.

### **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](http://www.genzyme.com).

### **About Sanofi**

Sanofi, a global and diversified 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).



### **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, 2011. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

Genzyme® is a registered trademark. All rights reserved.

Rebif® is a registered trademark of EMD Serono, Inc. or affiliates.

---

### **Contacts :**

#### **Sanofi Media Relations**

Jean-Marc Podvin  
Tel: +33 (0) 1 53 77 46 46  
E-mail: [mr@sanofi.com](mailto:mr@sanofi.com)

#### **Genzyme Media Relations**

Bo Piela  
Tel: +1 617 768 6579  
E-mail: [bo.piela@genzyme.com](mailto:bo.piela@genzyme.com)

#### **Sanofi Investor Relations**

Sébastien Martel  
Tel: +33 (0) 1 53 77 45 45  
E-mail: [ir@sanofi.com](mailto:ir@sanofi.com)

#### **Sanofi Investor Relations**

Kristen Galfetti  
Tel: +1 908 981 5560  
E-mail: [ir@sanofi.com](mailto:ir@sanofi.com)