

# Genzyme to Present New Data from AUBAGIO<sup>®</sup> and LEMTRADA<sup>TM</sup> Clinical Development Programs at ECTRIMS

- Depth and Breadth of data from the Genzyme MS Franchise Underscore Company's Commitment to Addressing Unmet Needs of People Living with Multiple Sclerosis -

**Paris, France – October 9, 2012 –** Genzyme, a Sanofi company (EURONEXT: SAN and NYSE: SNY), announced today new data from Genzyme's clinical development programs for AUBAGIO<sup>®</sup> (teriflunomide) and LEMTRADA<sup>TM</sup> (alemtuzumab) will be presented at the 28<sup>th</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Lyon, France, October 10-13.

"The data to be presented at ECTRIMS are a reflection not only of the comprehensive clinical development programs supporting AUBAGIO and LEMTRADA, but of the unique commitment and substantial progress Genzyme has made to date in bringing forward differentiated therapies in multiple sclerosis," said Genzyme CEO and President, David Meeker.

Once-daily, oral AUBAGIO is now commercially available in the U.S. following FDA approval in patients with relapsing forms of MS. Marketing applications for AUBAGIO and LEMTRADA are currently under review by the EMA and other regulatory authorities.

Key data from across the company's clinical development programs to be presented are as follows. Abstracts are available on the ECTRIMS website.

# TOWER (Teriflunomide Oral in people With relapsing multiplE scleRosis)

TOWER is a randomized Phase III trial assessing once-daily oral AUBAGIO (teriflunomide) in patients with relapsing multiple sclerosis. It is the second Phase III study for AUBAGIO.

 The efficacy and safety of teriflunomide in patients with relapsing MS: results from TOWER, a phase III, placebo-controlled study (Parallel Session 12 – 153; October 12; 3:10 p.m. CEST, 9:10 a.m. EDT).

## CARE-MS II (Comparison of Alemtuzumab and Rebif Efficacy in Multiple Sclerosis II)

CARE-MS II was a randomized Phase III clinical trial designed to evaluate whether the investigational MS therapy LEMTRADA (alemtuzumab) could achieve meaningful efficacy and safety improvements over the approved, active comparator Rebif (subcutaneous interferon beta-1a 44 mcg).

- Efficacy of alemtuzumab in relapsing-remitting multiple sclerosis patients who relapsed on prior therapy: subgroup analyses by previous DMT use (Poster Session 1 – P483; October 11; 3:30 p.m. CEST, 9:30 a.m. EDT).
- Disability improvement with alemtuzumab vs. interferon beta-1a in relapsing-remitting multiple sclerosis patients who relapsed on prior therapy (Poster Session 2 – P922; October 12; 3:30 p.m. CEST, 9:30 a.m. EDT).
- Effect of alemtuzumab vs. Rebif<sup>®</sup> on brain MRI measurements: (Poster Session 2 P877; October 12; 3:30 p.m. CEST, 9:30 a.m. EDT).
- Safety of alemtuzumab in relapsing-remitting multiple sclerosis patients who relapsed on prior therapy (Poster Session 1 – P545; October 11; 3:30 p.m. CEST, 9:30 a.m. EDT).



Additional Genzyme MS portfolio data, in addition to the Genzyme satellite symposia to be featured at ECTRIMS include:

#### **AUBAGIO:**

- Magnetic resonance imaging as a surrogate for clinical endpoints in multiple sclerosis (Poster Session 2 – P1014; October 12; 3:30 p.m. CEST, 9:30 a.m. EDT).
- Teriflunomide treatment of human monocyte-derived dendritic cells in vitro does not impair their maturation or ability to induce allogeneic T-cell responses (Poster Session 2 – P950; October 12; 3:30 p.m. CEST, 9:30 a.m. EDT).
- Effect of teriflunomide on immune responses to seasonal influenza vaccination in patients with relapsing multiple sclerosis: results from the TERIVA study (Poster Session 2 – P925; October 12; 3:30 p.m. CEST, 9:30 a.m. EDT).
- Effect of teriflunomide on the pharmacodynamic and pharmacokinetic profiles of warfarin in healthy male subjects (Poster Session 1 P453; October 11; 3:30 p.m. CEST, 9:30 a.m. EDT).
- Pregnancy outcomes from the teriflunomide clinical development programme: retrospective analysis of the teriflunomide clinical trial database (Poster Session 2 – P737; October 12; 3:30 p.m. CEST, 9:30 a.m. EDT).
- Effect of teriflunomide on lymphocyte and neutrophil levels in patients with relapsing multiple sclerosis: results from the TEMSO study (Poster Session 2 – P995; October 12; 3:30 p.m. CEST, 9:30 a.m. EDT).

## LEMTRADA:

- Autoimmunity in patients treated with alemtuzumab for relapsing-remitting multiple sclerosis (Poster Session 2 – P1005; October 12; 3:30 p.m. CEST, 9:30 a.m. EDT).
- Lymphocyte subset dynamics following alemtuzumab treatment in the CARE-MS I study (Poster Session 2 – P935; October 12; 3:30 p.m. CEST, 9:30 a.m. EDT).
- Therapeutic treatment with an anti-mouse CD52 antibody reverses disease symptoms in a murine EAE model of multiple sclerosis (Poster Session 2 – P908; October 12; 3:30 p.m. CEST, 9:30 a.m. EDT).

## Satellite Symposium

"MS Pathophysiology and Implications for Treatment"

When: Thursday, October 11; 12:45 – 1:45 p.m. CEST

Location: Amphitheatre

# **About AUBAGIO®** (teriflunomide)

The U.S. Food and Drug Administration (FDA) has approved AUBAGIO® (teriflunomide) as a oncedaily, oral immunomodulator indicated for patients with relapsing forms of multiple sclerosis (MS). The ongoing AUBAGIO clinical development program, involving more than 5,000 patients in 36 countries, is among the largest of any MS therapy. Some patients in extension trials have been treated up to 10 years.

AUBAGIO is an immunomodulator with anti-inflammatory properties. Although the exact mechanism of action for AUBAGIO is not fully understood, it may involve a reduction in the number of activated lymphocytes in the central nervous system (CNS).

Click <a href="http://products.sanofi.us/aubagio/aubagio.pdf">http://products.sanofi.us/aubagio/aubagio.pdf</a> for full Prescribing Information for once-daily oral AUBAGIO (teriflunomide



## **About Alemtuzumab/LEMTRADA™**

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 has the worldwide rights to alemtuzumab and has primary responsibility for its 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.

Lemtrada™ is the proprietary name submitted to health authorities for the company's investigational multiple sclerosis agent alemtuzumab.

## 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 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 forwardlooking 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, 2011. 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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Rebif<sup>®</sup> is a registered trademark of EMD Serono, Inc. or affiliates.

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