



# Sanofi and its subsidiary Genzyme to Feature More than 20 Data Presentations at the ECTRIMS/ACTRIMS Congress

# - Depth of Research, Including Pivotal Phase III Data for Lemtrada<sup>™</sup> and Aubagio<sup>™</sup>, Underscores Genzyme's Commitment to Patients with Multiple Sclerosis -

**Paris, France - October 18, 2011 -** Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today that more than 20 data presentations from the company's growing multiple sclerosis (MS) portfolio will be showcased at the 5<sup>th</sup> Joint Triennial Congress of the European and Americas Committees for Treatment and Research in Multiple Sclerosis (*ECTRIMS/ACTRIMS 2011*). Data to be presented will include new results from pivotal Phase III clinical trials of the company's lead investigational candidates for the treatment of relapsing MS, Lemtrada<sup>™</sup> (alemtuzumab) and Aubagio<sup>™</sup> (oral teriflunomide), and will be featured in platform and poster presentations.

"Genzyme is committed to transforming the landscape of MS treatment through novel research and development aimed at addressing significant unmet needs for patients with MS," said David Meeker, M.D., Chief Operating Officer, Genzyme. "With Lemtrada<sup>TM</sup> and Aubagio<sup>TM</sup> – two unique, promising investigational treatments – we hope to deliver advancement in MS treatment across the patient spectrum."

Following are select abstracts highlighting new data from the Phase III CARE-MS I study (The Comparison of Alemtuzumab and Rebif<sup>®</sup> Efficacy in Multiple Sclerosis) and the Phase III TEMSO trial (Study of Teriflunomide in Reducing the Frequency of Relapses and Accumulation of Disability in Patients With Multiple Sclerosis). Note that data is embargoed until the date and time of the presentation:

# Late-Breaker Oral Presentation for Lemtrada<sup>™</sup>:

• Efficacy and Safety Results from CARE-MS I: A Phase III Study Comparing Alemtuzumab and Interferon Beta-1a (Late-Breaker Oral Presentation 151; 22 October, 09:15-09:30 CEST)

# Expanded TEMSO Results for Aubagio<sup>™</sup>:

- Extension of a Phase III Trial (TEMSO) of Oral Teriflunomide in Multiple Sclerosis with Relapses: Clinical and MRI Data 5 Years After Initial Randomization (Poster 924; 21 October, 15:30-17:00 CEST)
- Efficacy of Oral Teriflunomide in Multiple Sclerosis with Relapses: Cognitive Outcomes from a Phase III Trial (TEMSO) (Poster 438; 20 October, 15:30-17:00 CEST)
- Extension of a Phase III Trial (TEMSO) of Oral Teriflunomide in Multiple Sclerosis with Relapses: Safety Outcomes with Up to 4 Years of Follow-Up (Poster 439; 20 October, 15:30-17:00 CEST)
- Effect of Teriflunomide on Relapses Leading to Healthcare Resource Use: Results from the TEMSO Study (Poster 250; 20 October, 15:30-17:00 CEST)



Following are additional, select abstracts from the Genzyme MS pipeline program:

# Lemtrada<sup>™</sup>:

- Alemtuzumab for Multiple Sclerosis in Patients Who Have Relapsed on Therapy: CARE-MS II Baseline Demographics and Disease Characteristics (Poster 928; 21 October, 15:30-17:00 CEST)
- Leukocyte Dynamics Following Alemtuzumab Treatment of Relapsing-Remitting Multiple Sclerosis: Long-term Follow-Up of CAMMS223 Patients (Poster 437; 20 October, 15:30-17:00 CEST)
- Alemtuzumab's Durable Efficacy in Multiple Sclerosis Four Years after Last Treatment Cycle (Poster 931; 21 October; 15:30-17:00 CEST)
- Analysis of Innate Immune Competence Following Alemtuzumab Treatment in Human CD52 Transgenic Mice (Poster 791; 21 October, 15:30-17:00 CEST)

## Aubagio<sup>™</sup>:

- Long-term Safety and Tolerability of Teriflunomide in Multiple Sclerosis: 9-Year Follow-Up of a Phase II Study (Poster 914; 21 October, 15:30-17:00 CEST)
- Efficacy of Teriflunomide in Relapsing Multiple Sclerosis: Phase II Extension Study with 8-Year Follow-Up (Poster 440; 20 October, 15:30-17:00 CEST)

\*Lemtrada<sup>TM</sup> and Aubagio<sup>TM</sup> are the proprietary names submitted to health authorities for the company's investigational multiple sclerosis agent alemtuzumab and teriflunomide respectively.

# About Lemtrada<sup>™</sup> (alemtuzumab)

Lemtrada is a humanized monoclonal antibody being studied as a potential therapy for relapsing MS. Lemtrada targets the cell-surface glycoprotein CD52, which is highly expressed on T- and B-lymphocytes. Preliminary research suggests that Lemtrada initially depletes the T- and B-cells that may be responsible for the cellular damage in MS. This depletion of T- and B-cells is followed by a distinctive pattern of lymphocyte repopulation. Lemtrada appears to have little or no effect on other cells of the immune system. In addition to the completed CARE-MS I study, another Phase III trial, CARE-MS II, will evaluate Lemtrada against interferon beta-1a in relapsing-remitting multiple sclerosis patients who have relapsed while on therapy, with top-line results expected to be available in the fourth quarter of 2011.

# About Aubagio<sup>™</sup> (teriflunomide)

Teriflunomide is an immunomodulatory, disease-modifying oral drug with anti-inflammatory properties, and is under investigation for the treatment of relapsing forms of MS. Teriflunomide blocks the proliferation and functioning of activated T and B lymphocytes – which are thought to be especially damaging in MS – by selectively and reversibly inhibiting a critical mitochondrial enzyme. With nine years of continuous use in a Phase II extension, teriflunomide has the longest clinical experience of any investigational oral MS therapy. In addition to the TEMSO trial, two other Phase III trials, TOWER and TENERE, are ongoing in people with relapsing MS. A Phase III study, TOPIC, is also underway in early MS or CIS (clinically isolated syndrome). Teriflunomide is also being evaluated as an adjunct therapy to interferon- $\beta$  in the Phase III TERACLES trial.

#### About Genzyme

One of the world's leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Since its founding in 1981, the company has introduced breakthrough treatments that have provided new hope for patients. The



company's areas of focus are rare genetic diseases, multiple sclerosis, cardiovascular disease, and endocrinology. Genzyme is a Sanofi company. Genzyme's press releases and other company information are available at www.genzyme.com.

Genzyme is responsible for the development of teriflunomide and alemtuzumab.

#### **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, rare diseases, consumer healthcare, emerging markets and animal health. 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 products candidates, the absence of guarantee that the products 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 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, 2010. 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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