## **PRESS RELEASE**



Because health matters



Sanofi-aventis

Media Contact:
Jean-Marc Podvin
+33 1 53 77 44 50

Investor Contact : Sébastien Martel +33 1 53 77 45 45 Genzyme
Media Contact:
John Lacey
617-768-6690
857-222-8589
Investor Contact:
Jennifer Murphy
617 768-6301

# Genzyme Presents New Data from Alemtuzumab Phase 2 MS Trial at 63rd Annual Meeting of the American Academy of Neurology

Paris, France and Cambridge, Mass. April 7, 2011 – Genzyme, a subsidiary of sanofi-aventis Group (EURONEXT: SAN and NYSE: SNY), announced today that it will present new data from its completed Phase 2 trial of the investigational drug alemtuzumab for multiple sclerosis (MS) at the American Academy of Neurology's (AAN) 63rd Annual Meeting in Hawaii, April 9 - 16, 2011. Included among the additional Phase 2 trial safety and efficacy data at AAN will be presentations on the clinically-active disease status of patients through five-years of patient follow-up as well as data describing a measure of vision improvement.

"We are excited to present new alemtuzumab data at AAN that further reflects alemtuzumab's potential as an MS treatment," said Michael Panzara, Genzyme Group Vice President and Therapeutic Area Head for Multiple Sclerosis and Immune Diseases. "We look forward to the availability of Phase 3 results in the middle of this year."

Alemtuzumab is a humanized monoclonal antibody being studied as a potential therapy for relapsing-remitting multiple sclerosis (RRMS). Genzyme is currently conducting two pivotal Phase 3 trials to evaluate alemtuzumab in the treatment of MS. CARE-MS I is a randomized trial comparing alemtuzumab to the approved MS therapy Rebif® (high dose interferon beta-1a) in early, active RRMS patients who have received no prior therapy. CARE-MS II, which also compares alemtuzumab to Rebif, is studying RRMS patients who relapsed while on other MS therapies. Data from these trials are expected to be available beginning in mid-2011.

Genzyme's CAMMS223 Phase 2 trial, first reported in the *New England Journal of Medicine* in 2008, compared alemtuzumab to Rebif in early, active, RRMS patients who had received no prior therapy. In the trial, which was larger and longer than most Phase 2 MS clinical trials, alemtuzumab was given to patients in two or three annual cycles of not more than five days per cycle, while Rebif was given to patients three times per week, every week for three years. The study included an extended phase for collection of long-term efficacy and safety data.

# Alemtuzumab data to be presented at AAN:

## Abstract titles

- More Alemtuzumab Relapsing-Remitting Multiple Sclerosis Patients Are Free of Clinical Disease Activity at Five Years (Poster PD6.003, April 14)
- Alemtuzumab Improves Contrast Sensitivity in Relapsing-Remitting Multiple Sclerosis Patients (Presentation S31.001, April 13)
- Alemtuzumab Positively Affects Disability Outcomes Using a One-Year-Sustained Criterion for Relapsing-Remitting Multiple Sclerosis Patients in CAMMS223 (Poster P01.216, April 11)
- Effect of Alemtuzumab vs. Interferon beta-1a on Brain Atrophy in Patients with Early, Active Relapsing-Remitting Multiple Sclerosis (Poster P05.042, April 13)
- Analysis of Innate Immune Cells Following Alemtuzumab Treatment in Human CD52 Transgenic Mice (Poster P02.201, April 12)
- Alemtuzumab and Thyroid Autoimmunity in Relapsing–Remitting Multiple Sclerosis Patients in CAMMS223 (Poster P03.242, April 12)

### **About Alemtuzumab**

Alemtuzumab is a humanized monoclonal antibody being studied as a potential therapy for relapsing-remitting multiple sclerosis. Alemtuzumab targets the cell-surface glycoprotein CD52, which is often expressed on T- and B-lymphocytes. Preliminary research suggests that alemtuzumab depletes the T- and B-cells that may be responsible for the cellular damage in MS, while potentially sparing other cells of the immune system. Early alemtuzumab research has also suggested a distinctive pattern of lymphocyte reconstitution in patients following treatment.

## **About CAMMS223 Phase 2 Study**

In the Phase 2 trial, 334 patients with early active relapsing-remitting multiple sclerosis were randomized to treatment with alemtuzumab at one of two dose levels, or to the approved MS therapy Rebif® (high dose interferon beta-1a). Alemtuzumab was given to patients in two or three annual cycles of not more than five days per cycle, while Rebif was given to patients three times per week, every week for three years. The majority of alemtuzumab treated patients last received the investigational drug at Month 12.

The trial successfully met its two primary endpoints, reduction in relapse rate and reduction in the rate of sustained accumulation of disability.

Patients were strongly encouraged to continue for two additional years of follow-up beyond the original three years of the study. Sixty-eight percent of alemtuzumab patients participated in the follow-up program, and 60 percent were evaluated at 60 months. Forty-two percent of Rebif patients participated in the follow-up program, and 35 percent were evaluated at 60 months. Rater-blinded disability scores were assessed quarterly and relapses as-needed. A sensitivity analysis adjusted for patients receiving alternative disease-modifying therapy during the follow-up period, as well as for retreatment with alemtuzumab.

## **Safety Information**

As previously reported, common adverse events associated with alemtuzumab in the CAMMS223 Phase 2 trial included mild to moderate infusion-associated reactions, secondary autoimmunity (primarily thyroid disorders and immune thrombocytopenia), and infections, particularly of the upper respiratory tract; infections were predominantly mild to moderate in severity and there were no life-threatening or fatal infections. Approximately 30 percent of alemtuzumab-treated patients developed an autoimmune thyroid-related adverse event. Thyroid disorders were managed using conventional therapies. Patient monitoring for thyroid disorders, ITP, and anti-

GBM disease is incorporated into all Genzyme-sponsored trials of alemtuzumab for the investigational treatment of MS.

Since it is not yet approved for the treatment of MS, alemtuzumab must not be used in MS patients outside of a formal, regulated clinical trial setting in which appropriate patient monitoring measures are in place.

# **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 across several areas of medicine that have provided new hope for patients. Today, approximately 10,000 Genzyme employees serve patients in nearly 100 countries.

Genzyme's products are focused on rare inherited disorders, kidney disease, orthopaedics, cancer, transplant, and immune disease. The company's commitment to innovation continues today with a substantial development program focused on these fields, as well as cardiovascular disease, neurodegenerative diseases, and other areas of unmet medical need. Genzyme is part of the sanofi-aventis Group.

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Genzyme's press releases and other company information are available at www.genzyme.com.

### **About sanofi-aventis**

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY). For more information, please visit: <a href="https://www.sanofi-aventis.com">www.sanofi-aventis.com</a>

### 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-aventis' 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-aventis, 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 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 sanofiaventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2010. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.