

PRESS RELEASE



Five-year Alemtuzumab Phase 2 Data Shows Large Percentage of MS Patients Remain Free of Clinically-Active Disease

- Alemtuzumab Seen to Improve Low-Contrast Vision -

- Data Presented at 63rd Annual Meeting of the American Academy of Neurology -

Paris, France – April 14, 2011 – Genzyme Corp., a subsidiary of sanofi-aventis Group (EURONEXT: SAN and NYSE: SNY), reported today additional five-year patient data from its completed Phase 2 multiple sclerosis (MS) trial showing that nearly two-thirds of alemtuzumab treated patients remained free of clinically-active disease as much as four years after most patients received their last course of the investigational drug. The data were presented at the American Academy of Neurology's 63rd Annual Meeting.

The CAMMS223 Phase 2 trial, first reported in the *New England Journal of Medicine* in 2008, compared alemtuzumab to the approved MS therapy Rebif® (high dose interferon beta-1a) in early, active, relapsing-remitting multiple sclerosis (RRMS) patients who had received no prior therapy. In the trial, 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.

Results of the five-year review showed:

- an estimated 65 percent of alemtuzumab-treated patients were free of clinically-active disease, compared to 27 percent of patients taking Rebif ($p < 0.0001$). To be free of clinically-active disease, MS patients in the trial were both relapse-free and without a sustained increase in disability as measured by the Expanded Disability Status Scale (EDSS) through five years;
- an estimated 72 percent of alemtuzumab-treated patients were relapse-free compared to 41 percent of patients taking Rebif; and
- an estimated 87 percent of alemtuzumab-treated patients were free of sustained accumulation of disability compared to 62 percent of patients taking Rebif (previously reported).

“These data suggest that alemtuzumab may have great potential for MS patients,” said abstract author Cary Twyman, MD, principal Investigator, Associates in Neurology, Lexington, KY.

Two pivotal Phase 3 studies investigating alemtuzumab, CARE-MS I and II, are currently ongoing. Top-line results from these trials are expected to be available respectively early in the third quarter of 2011 and in the fourth quarter of 2011. The company expects to file for U.S. and E.U. approval in early 2012, and has been granted fast track status by the FDA for this submission.

Alemtuzumab Seen to Improve Low-Contrast Vision

Visual impairment is a common complication of multiple sclerosis. A second abstract presented at AAN reported that sustained improvement in visual contrast sensitivity, as measured by low-contrast letter testing, was more than twice as likely for those patients in the Phase 2 trial receiving the investigational drug alemtuzumab compared to patients receiving the active comparator Rebif.

“Low-contrast letter acuity exams are a sensitive way of measuring visual function in MS clinical trials, and can correlate well with structural markers of the disease,” said abstract author Laura Balcer, MD, Associate Professor of Neurology, University of Pennsylvania School of Medicine. *“The improvements seen with alemtuzumab treatment as compared with interferon beta are encouraging.”*

During the trial, patients were asked to identify letters on low-contrast letter charts, which capture the minimum size at which individuals can perceive letters of a particular contrast level (shade of gray on white background). Low-contrast sensitivity was measured for each eye at baseline and quarterly thereafter by masked raters.

The analysis found that alemtuzumab patients were more than twice as likely to experience sustained improvement in vision as compared to Rebif patients ($p=0.012$). Alemtuzumab patients also realized a 46 percent reduction in the risk of sustained worsening in vision as compared to Rebif treated patients ($p=0.0028$).

These data expand upon disability improvements as measured by the Expanded Disability Status Scale (EDSS). The EDSS is a 10-point scale in which every 0.5-point step marks a notable deterioration in neurological capabilities. In the Phase 2 trial, as previously reported at month 36 and 60 the mean EDSS disability score of patients receiving alemtuzumab improved, while the mean disability worsened in the comparator group.

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.

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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.

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: www.sanofi-aventis.com

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 sanofi-aventis, 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.

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