



Alemtuzumab (Lemtrada™) Significantly Reduces Relapses in Multiple Sclerosis vs Interferon Beta-1a in a Phase III Study

- New data from CARE-MS I presented at the 5thECTRIMS/ACTRIMS Congress -

- Data shows 78 percent of patients treated with alemtuzumab remained relapse-free for two years compared with patients on high dose IFNβ-1a -

Paris, France - October 22, 2011 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today new results from the CARE-MS I trial, the first of two randomized, Phase III clinical trials comparing the investigational drug alemtuzumab (Lemtrada™) to Rebif® (high dose subcutaneous interferon beta-1a) in patients with relapsing-remitting multiple sclerosis (MS). New data show that 78 percent of patients treated with alemtuzumab remained relapse-free for two years, providing statistically significant improvement over interferon beta-1a (78 percent vs 59 percent at two years, $p < 0.0001$) and meeting this secondary endpoint. The CARE-MS I results were presented today at the 5th Joint Triennial Congress of the European and Americas Committees for Treatment and Research in Multiple Sclerosis (ECTRIMS/ACTRIMS). Genzyme is developing alemtuzumab for relapsing MS in collaboration with Bayer HealthCare.

As previously reported, treatment with alemtuzumab resulted in a 55 percent reduction in relapse rate compared to interferon beta-1a over two years of study ($p < 0.0001$), satisfying this co-primary endpoint and meeting the predefined protocol criteria for declaring the study a success. At the two-year time point, very few alemtuzumab patients (8 percent) experienced a sustained increase, or worsening, in disability as measured by the Expanded Disability Status Scale (EDSS) (vs 11 percent of patients in the interferon beta-1a group). However, the difference between groups for this co-primary endpoint were not statistically significant ($p = 0.22$) and there was no difference in the mean EDSS score between groups.

The CARE-MS I trial compared treatment with alemtuzumab (12 mg/day by IV administration for 5-days, with a second 3-day IV administration one year later), to treatment with subcutaneous interferon beta-1a (44 mcg administered by injection three times per week) in 581 patients with relapsing-remitting MS who had received no previous treatment to suppress MS, except for steroids.

“CARE-MS I confirms that, in a head-to-head comparison with Rebif, disease activity is significantly reduced in patients with early relapsing-remitting multiple sclerosis treated with alemtuzumab, over the first two years of observation,” said Professor Alastair Compston, Chair of the Steering Committee overseeing the conduct of the study and head of the Department of Clinical Neurosciences at the University of Cambridge, United Kingdom. *“These data support the robust efficacy profile and potential that alemtuzumab offers for patients with relapsing-remitting multiple sclerosis requiring a more effective option than currently available therapies.”*

“Lemtrada’s robust effects over and above those of Rebif on relapses and a variety of clinical and imaging endpoints reinforces its potential as an effective treatment option for MS patients,” said David Meeker, M.D., Chief Operating Officer, Genzyme. *“We look forward to the results of CARE-MS II, our*



second Phase III study, later this year to extend these results by confirming Lemtrada's effects in patients with continued disease activity while receiving another MS treatment."

Additional findings from the CARE-MS I study presented today include other secondary endpoints that suggest positive outcomes with alemtuzumab. Improvement in Multiple Sclerosis Functional Composite (MSFC) scores was observed in alemtuzumab-treated patients, as compared to interferon beta-1a (0.12 vs 0.05 mean change from baseline at year two, $p=0.012$). MSFC is a composite measurement of physical and cognitive function.

The effect of alemtuzumab on reduction in T2-hyperintense lesion volume compared to interferon beta-1a was -9.3 vs -6.5 median percent change at year two ($p=0.31$). Other MRI outcomes suggested that alemtuzumab provided improvement over interferon beta-1a across a number of image-related endpoints, generally consistent with the effects observed in the clinical endpoints. Statistically significant improvement was observed for alemtuzumab over interferon beta-1a in the percentage of patients with new and enlarging T2-hyperintense lesions (49 vs 58, $p=0.035$); with new gadolinium-enhancing lesions (15 vs 27, $p=0.0006$); and with new T1-hypointense lesions (24 vs 31, $p=0.05$). In addition, alemtuzumab-treated patients experienced less change in brain parenchymal fraction (BPF), a measure of brain atrophy, compared to interferon beta-1a (-0.87 vs -1.49 median percent change from baseline, $p<0.0001$), a highly statistically significant result.

CARE-MS I Safety Findings

Common adverse events associated with alemtuzumab in the CARE-MS I study included infusion-associated reactions which were generally mild to moderate. Additionally, the incidence of infections was increased, the most common infections involving the upper respiratory and urinary tract and oral herpes. Infections were predominantly mild to moderate in severity and none were life-threatening or fatal.

The incidence of serious adverse events was similar between the two treatment arms (18.4 percent for alemtuzumab vs 14.4 percent for interferon beta-1a). Relating to autoimmune disorders, 18.1 percent of alemtuzumab-treated patients developed an autoimmune thyroid-related adverse event and 0.8 percent developed immune thrombocytopenia (ITP) during the two-year study period. There were no cases of anti-GBM disease. Cases of autoimmunity were detected and managed using conventional therapies. Patient monitoring for immune cytopenias and thyroid or renal disorders is incorporated in all Genzyme-sponsored trials of alemtuzumab for the investigational treatment of multiple sclerosis.

Additional Information

Another Phase III clinical trial, CARE-MS II, is currently underway, evaluating alemtuzumab against interferon beta-1a in relapsing-remitting MS patients who have relapsed while on therapy. Top-line results from that trial are expected to be available in the fourth quarter of 2011.

The company expects to file for U.S. and E.U. approval of alemtuzumab in relapsing MS in the first quarter of 2012, and alemtuzumab has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA). 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.

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

About the CARE-MS I Trial

CARE-MS I (The Comparison of alemtuzumab and Rebif® Efficacy in Multiple Sclerosis) trial was designed to evaluate whether the investigational MS therapy alemtuzumab could achieve meaningful



efficacy and safety improvements over the approved, active comparator interferon beta-1a, a standard treatment for relapsing MS.

CARE-MS I was a Phase III, global, randomized clinical trial comparing treatment with alemtuzumab (12 mg/day for a 5-day IV administration, with a second 3-day IV administration one year later), to treatment with subcutaneous interferon beta-1a (44 mcg administered by injection three times per week) in 581 patients with relapsing-remitting MS who had received no previous treatment to suppress MS, except for steroids. Patients were randomized at a ratio of 2 to 1 to receive alemtuzumab or interferon beta-1a. Co-primary efficacy endpoint assessments were performed at regularly scheduled visits by independent, evaluating neurologists who were blinded to the patients' treatment assignments.

The CARE-MS I trial had co-primary endpoints: reduction in relapse rate and six months sustained accumulation of disability (SAD)[†]. Based on the criteria set forth in the study protocol, CARE-MS I is defined as a success if both co-primary endpoints are met ($p \leq 0.05$) or if one co-primary endpoint is met against a more stringent measure of statistical significance ($p \leq 0.025$). Secondary outcome measures include: Percentage of relapse-free patients at year two; Expanded Disability Status Scale (EDSS) change from baseline; Percent change in magnetic/resonance imaging (MRI)-T2-hyperintense lesion volume at year two; and Multiple Sclerosis Functional Composite (MSFC) change from baseline.

[†]Sustained Accumulation of Disability (SAD) – Clinical representation of the worsening of a patient's level of disability; CARE-MS I monitored this endpoint over the course of six months.

About Alemtuzumab

Alemtuzumab is a humanized monoclonal antibody being studied as a potential therapy for relapsing MS. Alemtuzumab targets the cell-surface glycoprotein CD52, which is highly expressed on T- and B-lymphocytes. Preliminary research suggests that alemtuzumab 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. Alemtuzumab 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 alemtuzumab against interferon beta-1a in relapsing-remitting MS patients who have relapsed while on therapy.

Genzyme has the worldwide rights to alemtuzumab and has primary responsibility for the development and commercialization of alemtuzumab 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 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 in the fields of rare inherited disorders, kidney disease, orthopaedics, cancer, transplant, and immune diseases. Genzyme is a Sanofi company. Genzyme's press releases and other company information are available 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, rare diseases, consumer healthcare, emerging markets and animal health. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).



About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of more than EUR 16.913 billion (2010), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55.700 employees and is represented in more than 100 countries. Find more information at www.bayerhealthcare.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'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 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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