



Significant Improvement in Disability Scores Observed in Multiple Sclerosis Patients Who Received Lemtrada™* (Alemtuzumab) Compared With Rebif® in Phase III Trial

- Patients treated with alemtuzumab in CARE-MS II were more than twice as likely to experience disability improvement compared to Rebif -

Paris, France - April 24, 2012 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme report today additional data from the Phase III CARE-MS II trial. Accumulation of disability was significantly slowed in patients with multiple sclerosis (MS) who were treated with alemtuzumab versus Rebif® (high dose subcutaneous interferon beta-1a), as measured by the Expanded Disability Status Scale (EDSS), a standard assessment of physical disability progression. In addition, significant improvement in disability scores was observed in some patients treated with alemtuzumab from baseline and compared to patients treated with Rebif, suggesting a reversal of disability in these patients. In the trial, patients with pre-existing disability treated with alemtuzumab were more than twice as likely to experience a sustained reduction in disability than patients given Rebif. Genzyme is developing alemtuzumab in MS in collaboration with Bayer HealthCare.

CARE-MS II was a randomized Phase III clinical trial comparing the investigational drug alemtuzumab to Rebif in patients with relapsing-remitting multiple sclerosis (RRMS) who had relapsed while on prior therapy. The company announced in November that results for the co-primary endpoints of the trial were highly statistically significant.

Key disability data from the CARE-MS II trial presented today at the 64th Annual Meeting of the American Academy of Neurology include:

- The mean EDSS score for patients treated with alemtuzumab decreased over a two-year period, indicating an improvement in their physical disability, while the mean score for patients given Rebif increased, indicating a worsening of disability (-0.17 vs. 0.24; $p < 0.0001$).
- At two years, 29 percent of patients treated with alemtuzumab had experienced a six-month sustained reduction in disability, meaning their level of disability improved, as compared to only 13 percent with Rebif ($p=0.0002$).
- There was a 42 percent reduction in the risk of six-month sustained accumulation (worsening) of disability (SAD) as measured by EDSS in patients treated with alemtuzumab compared to Rebif over two years of study ($p=0.0084$), as previously reported. This was a highly statistically significant result for this co-primary endpoint.

Key relapse data from the trial presented at AAN include:

- 65 percent of patients treated with alemtuzumab were relapse-free at two years, meaning they did not experience any relapses in the trial, compared to 47 percent with Rebif (47 percent risk reduction; $p<0.0001$).
- A 49 percent reduction in relapse rate was observed in patients treated with alemtuzumab 12 mg compared to Rebif over two years of study ($p<0.0001$), a highly significant result for this co-primary endpoint, as previously reported.

"To date, a key goal for MS treatment has been to delay the worsening of disability," said Jeffrey Cohen, M.D., Director of Experimental Therapeutics, Cleveland Clinic Mellen Center for MS Treatment and Research; and a member of the Steering Committee overseeing the conduct of the



study. *“Patients in the study whose prior MS treatment was inadequate at preventing relapses and received alemtuzumab in the CARE-MS II trial experienced a slowing or reversal of their disability.”*

In the CARE-MS II trial, alemtuzumab 12 mg was given as an IV administration a total of eight times over the course of the two-year study. The first treatment course of alemtuzumab was administered on five consecutive days, and the second course was administered on three consecutive days 12 months later. Rebif 44 mcg was administered by subcutaneous injection three times per week, each week, throughout the two years of study.

“Alemtuzumab is the first disease modifying therapy to show a significant effect both on relapse and disability endpoints over and above those of Rebif in a comparative trial,” said Professor Alastair Compston, Chair of the Steering Committee overseeing the conduct of the study, principal investigator on the phase II and III clinical trials of alemtuzumab, and Head of the Department of Clinical Neurosciences at the University of Cambridge, United Kingdom. *“The efficacy data from the CARE-MS trial program suggest that, if approved, alemtuzumab will be an important new treatment for relapsing MS patients with active disease.”*

Additional new data from the CARE-MS II study suggest that alemtuzumab provided significant improvement over Rebif across a number of imaging endpoints, consistent with the effects observed in the clinical endpoints. In MS, imaging can be used to track the development of lesions, or patches of inflammation in the central nervous system (CNS). Statistically significant improvement was observed for alemtuzumab over Rebif in the percentage of patients with new or enlarging T2-hyperintense lesions (46 vs. 68; $p < 0.0001$) and with gadolinium-enhancing lesions (19 vs. 34; $p < 0.0001$). The change in T2-hyperintense lesion volume from baseline to year two, a secondary endpoint, was not significantly different ($p = 0.14$). In the trial, patients treated with alemtuzumab experienced less change in brain parenchymal fraction (BPF), a measure of brain atrophy or loss of neurons and the connections between them, compared to Rebif (-0.62 vs. -0.81) median percent change from baseline ($p = 0.012$), a significant result.

“We believe these ground-breaking results from CARE-MS II, including reversal of disability accumulation in some patients, achieved over the standard therapy Rebif, provide a message of hope for people living with MS,” said David Meeker, M.D., President and CEO, Genzyme. *“We are on track to submit alemtuzumab for review to U.S. and EU regulatory authorities in the second quarter of this year and are excited about the potential of bringing this important therapy to people living with MS who have unmet treatment needs.”*

The most common adverse events associated with alemtuzumab in the CARE-MS II study were infusion-associated reactions, which were generally mild to moderate. Infections were common in both groups, with a higher incidence in the alemtuzumab group. The most common infections included upper respiratory and urinary tract infections, cutaneous fungal infections and oral herpes. Serious infections occurred in 3.7 percent of the alemtuzumab group as compared to 1.5 percent of the Rebif group. Infections were predominantly mild to moderate in severity and none were fatal.

In the trial, 15.9 percent of alemtuzumab-treated patients developed an autoimmune thyroid-related adverse event compared to 5.0 percent with Rebif, and 0.9 percent of alemtuzumab-treated patients developed immune thrombocytopenia (ITP) during the two-year study period. These cases were detected early through a monitoring program and managed using conventional therapies. Patient monitoring for ITP and thyroid or renal disorders is incorporated in all Genzyme-sponsored trials of alemtuzumab for the investigational treatment of MS. All data reported above pertain to patients in the trial who received alemtuzumab 12 mg or Rebif 44 mcg.

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.

The company is on track to file for U.S. and EU approval of alemtuzumab in relapsing MS in the second quarter of 2012. 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.

Sanofi will host a conference call for the financial community during the upcoming American Academy of Neurology Annual Meeting, including the results of the CARE - MS II study.

It will take place on Wednesday 25th April, 2012 at:
15:00 Paris CEST / 14:00 London BST/ 9.00 New York EDT

The conference call will include a presentation followed by a Q&A session.
It will be accessible through audio webcast at www.sanofi.com
and via the following telephone numbers.

CALL IN NUMBERS

France +33 (0) 1 70 77 09 38
UK +44 (0) 203 367 9457
USA +1 866 907 5925

AUDIO REPLAY

An audio replay of the call will be available through the numbers below.
The replay will be available approximately 2 hours after the end of the call.

France +33 (0) 1 72 00 15 00
UK +44 (0) 203 367 9460
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About CARE-MS

CARE-MS II (Comparison of Alemtuzumab and Rebif Efficacy in Multiple Sclerosis II) trial was designed to evaluate whether the investigational MS therapy alemtuzumab could achieve meaningful efficacy and safety improvements over the approved, active comparator Rebif (subcutaneous interferon beta-1a 44 mcg), a standard treatment for relapsing-remitting MS. Patients enrolled in the trial had to have active MS, with at least one relapse occurring while on MS therapy, including standard injectable disease modifying therapies.

CARE-MS II was a Phase III, global, randomized clinical trial comparing treatment with alemtuzumab to treatment with Rebif in 840 patients who relapsed while receiving prior MS treatment. The trial had two co-primary endpoints: reduction in relapse rate and six-months sustained accumulation of disability (SAD). 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. Disability assessments were performed at regularly scheduled visits by independent, evaluating neurologists who were blinded to the patients' treatment assignments. Relapse was determined by a blinded committee.

In addition to the completed CARE-MS II study, another Phase III trial, CARE-MS I, evaluated alemtuzumab against Rebif in relapsing-remitting MS patients naive to prior treatment and found a statistically significant reduction in relapse rate with alemtuzumab. In both trials, alemtuzumab 12 mg was given as an IV administration for a total of eight times over the course of the two-year study. The first treatment course of alemtuzumab was administered on five consecutive days, and the second course was administered on three consecutive days 12 months later. Rebif 44 mcg was administered by subcutaneous injection three times per week, each week, throughout the two years of study. In CARE-MS II, a third group of patients received alemtuzumab 24 mg (n=170), given on the same dosing schedule as the patients receiving alemtuzumab 12 mg (n=426).

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.

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).

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 EUR 17.2 billion (2011), 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, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2011) 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 labelling 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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Contacts :

Sanofi Media Relations

Jean-Marc Podvin
Tel: +33 (0) 1 53 77 46 46
E-mail: mr@sanofi.com

Genzyme Media Relations

Bo Piela
Tel: +1 617 768 6579
Mobile: +1 508 308 9783
E-mail: bo.piela@genzyme.com

Sanofi Investor Relations

Sébastien Martel
Tel: +33 (0) 1 53 77 45 45
E-mail: ir@sanofi.com

Sanofi Investor Relations

Kristen Galfetti
Tel: +1 908 981 5560
E-mail: ir@sanofi.com