Sanofi Reports Positive Top-Line Results from First Phase 3 Study of Alemtuzumab (Lemtrada™ (*)) in Multiple Sclerosis

- 55 percent relapse rate reduction over and above high dose IFNβ-1a in treatment naïve MS patients -

Paris, France - July 11, 2011 - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today positive top-line results from CARE-MS I, the first of two randomized, Phase 3 clinical trials comparing the investigational drug alemtuzumab to the approved multiple sclerosis therapy Rebif® (high dose subcutaneous interferon beta-1a) in patients with relapsing-remitting multiple sclerosis (RRMS). Genzyme is developing alemtuzumab in MS in collaboration with Bayer HealthCare.

In the CARE-MS I trial, 2 annual cycles of alemtuzumab treatment resulted in a 55 percent reduction in relapse rate compared to Rebif® over the two years of the study ($p<0.0001$), hence satisfying the first primary endpoint, and therefore meeting the predefined protocol criteria for declaring the study a success. Statistical significance was not achieved for the second primary endpoint, time to six month sustained accumulation of disability, as compared to Rebif®. At the two year time point, 8 percent of alemtuzumab treated patients had a sustained increase in their Expanded Disability Status Scale (EDSS) score (or worsening) as compared to 11 percent of those who received Rebif® (Hazard Ratio=0.70, $p=0.22$). The patients will have the option to be evaluated over the next 3 years as part of a separate protocol.

"The substantial effect of alemtuzumab on reduction of relapse rate over and above that seen with Rebif® *confirms our experience gathered over many years and demonstrated in the Phase 2 study,"* 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. *"We treated patients in CARE-MS I at a very early stage in the course of their illness when the natural history may be relatively quiet, and both groups were remarkably stable over the two years of observation. Very few patients accumulated disability at the rate expected from previous clinical trials, including our Phase 2 experience. Whilst welcome from the clinical perspective, this much reduced our ability to detect a significant treatment effect on the disability endpoint*."

"In this 2-year comparative study, the effect of alemtuzumab on reducing relapses versus Rebif, a leading drug for the treatment of Multiple Sclerosis, is impressive, and the safety profile is consistent with the Phase 2 clinical trial experience," said Christopher A. Viehbacher, Chief Executive Officer, Sanofi. *"We look forward to the results from CARE-MS II, which will provide clinical data in patients whose disease was not adequately controlled on other multiple sclerosis therapies. Today's results are an important step forward in the development of alemtuzumab to address the substantial unmet needs for multiple sclerosis patients."*

The most common adverse events associated with alemtuzumab in the CARE-MS I study included infusion-associated reactions, the symptoms of which most commonly included headache, rash, fever, nausea, flushing, hives and chills. The incidence of infections was also increased, the most common infections involving the upper respiratory and urinary tract and oral herpes. Infections were predominantly mild to moderate in severity and there were no life-threatening or fatal infections.

No alemtuzumab patient discontinued from the study due to an adverse event. Less than 20 percent of alemtuzumab-treated patients developed an autoimmune thyroid-related adverse event and less than 1 percent developed immune thrombocytopenia during the 2 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 MS. Analysis of the full CARE-MS I data is ongoing.

CARE-MS I, which enrolled 581 early, active RRMS patients who had received no prior MS therapy, was a global, randomized, rater-blinded clinical trial to determine the efficacy and safety of alemtuzumab in this population. The company anticipates presenting detailed CARE-MS I study findings at a medical meeting later this year.

Another Phase 3 clinical trial, CARE-MS II, is currently underway, evaluating alemtuzumab against Rebif® in relapsing-remitting multiple sclerosis patients who have relapsed while on therapy. Top-line results from that trial are expected to be available in the fourth quarter of 2011. 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.

The company expects to file for U.S. and E.U. approval of alemtuzumab in MS in early 2012, and has been granted fast track designation by the FDA.

(*) Lemtrada™ is the registered name submitted to health authorities for the investigational agent alemtuzumab.

About the CARE-MS I Trial

CARE-MS I (Comparison of Alemtuzumab and Rebif® Efficacy in Multiple Sclerosis, Study One) was a global, randomized, rater-blinded clinical trial comparing two annual cycles of intravenous alemtuzumab, 12 mg/day for 5 days initially and for 3 days a year later, to three-times weekly subcutaneous interferon beta-1a (Rebif®) in treatment-naïve patients with RRMS. The study enrolled 581 patients who had not previously received treatment to suppress MS, except steroids. The study's primary outcome measures were reduction in relapse rate and time to sustained accumulation of disability. Secondary outcome measures include: Proportion of patients who are relapse-free at year two; Change from baseline in Expanded Disability Status Scale; Acquisition of disability as measured by change from baseline in Multiple Sclerosis Functional Composite; and Percent change from baseline in magnetic*/ resonance imaging (MRI)-T2 hyperintense lesion volume at year two. Additional endpoints included the safety and tolerability of alemtuzumab.

About Alemtuzumab

Alemtuzumab is a humanized monoclonal antibody being studied as a potential therapy for relapsing forms of multiple sclerosis. Alemtuzumab targets the cell-surface glycoprotein CD52, which is highly 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 repopulation following alemtuzumab treatment.

About the Alemtuzumab Development Partnership

Genzyme has the worldwide rights to alemtuzumab and has primary responsibility for the development and commercialization of alemtuzumab in multiple sclerosis (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

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.

Sanofi 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.

Contacts:

Genzyme Media Relations
John Lacey
Tel: +1 617 768 6690
Mobile: +1 857 222 8589
E-mail: john.lacey@genzyme.com

Sanofi Media Relations
Marisol Péron
Tel: +33 (0) 1 53 77 45 02
Mobile: +33 (0) 6 08 18 94 78
E-mail: marisol.peron@sanofi.com

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