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Once-daily AUBAGIO® Delayed Onset of Clinically Definite Multiple Sclerosis (MS) in TOPIC Study

- Only Marketed Oral MS Therapy with Positive Data in Patients who Experienced Initial Attack Suggestive of MS -

Paris, France – April 25, 2013 – Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today positive top-line results from the TOPIC trial for AUBAGIO (teriflunomide). The trial was designed to assess whether early initiation of AUBAGIO (teriflunomide) in patients who experienced their first neurological symptoms consistent with Clinically Isolated Syndrome (CIS) can prevent or delay conversion to clinically definite multiple sclerosis (CDMS).

Clinically isolated syndrome (CIS) is defined as a first clinical attack with features suggestive of MS. It typically occurs in young adults and is often a prelude to CDMS.

In the TOPIC trial, patients receiving AUBAGIO 14 mg and 7 mg were significantly less likely to develop CDMS, defined as occurrence of a second clinical attack, the primary endpoint, as compared to placebo. Additional results, including key secondary and tertiary objectives, will be presented at a forthcoming scientific meeting.

Primary results were:

- In patients who received AUBAGIO 14 mg, a 43 percent reduction in risk of conversion to CDMS was observed over the two-year study period, compared to placebo (p=0.0087);
- In patients who received AUBAGIO 7 mg, a 37 percent reduction in risk of conversion to CDMS was observed over the two-year study period, compared to placebo (p=0.0271).

"Clinically Isolated Syndrome (CIS) is often a prelude to clinically definite multiple sclerosis, and early treatment has proved beneficial," said Dr. Aaron E. Miller, Medical Director, The Corinne Goldsmith Dickinson Center for Multiple Sclerosis, Mount Sinai Medical Center. *"These findings are important as there is an unmet need for an efficacious oral option for patients at this stage of disease."*

The average duration of AUBAGIO exposure in TOPIC was approximately 16 months. Adverse events observed in the trial were consistent with previous clinical trials with AUBAGIO in MS. The most common types of adverse events reported more frequently in the AUBAGIO arms were ALT (Alanine transaminase) elevations, nasopharyngitis, headache, hair thinning, diarrhea and paresthesia. There were no deaths reported in either teriflunomide group over the course of the study. There was one death due to suicide in the placebo arm. The rate of treatment discontinuation due to adverse events was similar across treatment arms (9.1 percent in placebo arm, compared to 12.1 percent in 7 mg teriflunomide arm and 8.3 percent in 14 mg teriflunomide arm).

"AUBAGIO is the only oral marketed MS therapy to successfully be studied in CIS and we are very pleased by these topline results which further reinforce the consistent efficacy and potential for treating a broad spectrum of MS patients," said Genzyme President and CEO, David Meeker, MD. *"We remain committed to addressing unmet needs in MS through new areas of research and delivery of differentiated therapies for this devastating disease."*

The trial compared treatment with either 14 mg or 7 mg once-daily, oral AUBAGIO against placebo. This double-blind, multi-center trial enrolled 618 patients who had experienced a first acute or sub-acute, well-defined neurological event consistent with demyelination, as well as onset of MS symptoms within 90 days of randomization, and MRI scan showing two or more T2 lesions characteristic of MS.

AUBAGIO is approved in the U.S., Australia and Argentina for the treatment of relapsing forms of MS. Marketing applications for AUBAGIO are also under review by regulatory authorities globally.

The ongoing AUBAGIO clinical development program, involving more than 5,000 patients in 36 countries, is amongst the largest of any MS therapy. Some patients in extension trials have been treated for up to 10 years.

About AUBAGIO®

AUBAGIO is an immunomodulator with anti-inflammatory properties. Although the exact mechanism of action for AUBAGIO is not fully understood, it may involve a reduction in the number of activated lymphocytes in the central nervous system (CNS).

Indications and Usage

AUBAGIO (teriflunomide) is a once-daily, oral treatment indicated for patients with relapsing forms of multiple sclerosis (MS). AUBAGIO 14 mg has shown significant efficacy across key measures of MS disease activity, including reducing relapses, slowing the progression of physical disability, and reducing the number of brain lesions as detected by MRI.

Important Safety Information About AUBAGIO

The AUBAGIO U.S. label includes a boxed warning citing the risk of hepatotoxicity and, teratogenicity (based on animal data).

In MS clinical studies with AUBAGIO, the incidence of serious adverse events were similar among AUBAGIO and placebo-treated patients. The most common adverse events associated with AUBAGIO in MS patients included increased ALT levels, alopecia, diarrhea, influenza, nausea and paresthesia.
Teriflunomide is the principal active metabolite of leflunomide, which is indicated in the U.S. for the treatment of rheumatoid arthritis. Severe liver injury including fatal liver failure has been reported in patients treated with leflunomide.

Leflunomide has greater than 2.1 million patient years of exposure in rheumatoid arthritis globally since its launch.

AUBAGIO is contraindicated in pregnant women and women of childbearing potential who are not using reliable contraception.

For full prescribing information and more information about AUBAGIO, please visit www.genzyme.com.

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).

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 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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