

Investigational Oral Multiple Sclerosis Therapy Teriflunomide (Aubagio™ (*)) Significantly Reduced Relapse Rate, Disability Progression and Disease Activity

- Findings from Two-Year Pivotal Phase III TEMSO Trial Published today in The New England Journal of Medicine -

PARIS, Oct. 6, 2011 /CNW/ - Sanofi (EURONEXT: SAN and NYSE: SNY) and its subsidiary Genzyme announced today the publication of the pivotal Phase III TEMSO study with investigational once-daily oral medication teriflunomide in The New England Journal of Medicine (NEJM). Results showed that teriflunomide at the 14mg dosage significantly reduced the annual relapse rate, reduced disability progressions and improved several magnetic resonance imaging (MRI) measures of disease activity, including new or worsening brain lesions. Teriflunomide has a well-characterized safety profile, with a similar proportion of trial participants reporting adverse events compared to placebo.

"The TEMSO data demonstrate the effect of teriflunomide in terms of reducing relapse rates, disability progression and Magnetic Resonance Imaging (MRI) lesions," said Dr. Paul O'Connor, Director of the MS Clinic at St Michael's Hospital, Toronto, Canada and principal investigator in the TEMSO study. "These results, sustained over two years, provide clinically meaningful data for teriflunomide."

The two-year TEMSO (**TE**riflunomide **M**ultiple **S**clerosis **O**ral) trial involved 1,088 people with relapsing forms of MS from 126 centers across 21 countries. TEMSO is the first study from a broad clinical development program that includes more than 4,000 trial participants in 36 countries and is one of the largest and broadest clinical programs of any oral MS agent under development, with five Phase III clinical trials either completed or underway.

"The publication of the teriflunomide results in the New England Journal of Medicine is an exciting milestone as we continue the development of our product," said Dr. Elias Zerhouni, President, Global Research & Development, Sanofi. "As we continue our commitment to research, innovation and the Multiple Sclerosis community, we look forward to providing therapeutic options for patients across the Multiple Sclerosis spectrum."

Teriflunomide has been filed with the FDA in August of 2011 and the EMA filing is expected in the first quarter of 2012. The results from the TEMSO study are and will be included in each regulatory submission.

TEMSO findings showed that, compared to placebo, teriflunomide once daily:

- Significantly reduced the risk of annual relapses, the primary endpoint, by 31% (both $p < 0.001$) for 7mg and 14mg doses.
- Significantly increased the time to first relapse, and allowed significantly more trial participants to remain free of relapses during the two years of the study: 53.7% (7mg, $p = 0.01$ vs. placebo), 56.5% (14mg, $p = 0.003$ vs. placebo) and 45.6% (placebo).
- The risk of 12-week confirmed disability progression, the key secondary endpoint, was significantly reduced by 30% ($p = 0.03$) for the 14mg dose and numerically reduced by 24% ($p = 0.08$) for the 7mg dose.
- Improved several standard magnetic resonance imaging (MRI) measures of disease activity as compared to placebo including new or worsening brain lesions with an apparent dose dependent effect in favor of the 14mg dose:
 - Reduced burden of disease (by 39.4% [$p = 0.03$] and 67.4 % [$p < 0.001$] for 7mg and 14mg, respectively)
 - Reduced gadolinium-enhancing T1 lesions (relative risk reduction of 57% and 80%, $p < 0.001$ for both doses);
 - Reduced unique active lesions per scan (relative risk reduction of 48% and 69%, $p < 0.001$ for both doses).

Similar adverse events, serious adverse events, and adverse events leading to treatment discontinuation were observed with teriflunomide compared to placebo. No serious or opportunistic infections and no deaths occurred in trial participants treated with teriflunomide. The proportion of participants who discontinued the study medication because of disease progression was significantly smaller in the group receiving the 14mg of teriflunomide than in the placebo group ($p = 0.02$). Malignancies were reported in three participants in the placebo group and one in the teriflunomide 14mg group.

Teriflunomide adverse events were usually of mild to moderate intensity, managed with existing therapies and rarely led to treatment discontinuation. The most common were diarrhea, nausea, liver enzyme increases (that

were mainly mild and asymptomatic with no dose effect) and mild hair thinning/decreased hair density. In general, diarrhea, nausea and alopecia, were mild to moderate, transient, and infrequently led to treatment discontinuation.

About Teriflunomide

Teriflunomide is an immunomodulatory, disease-modifying oral drug with anti-inflammatory properties, and is under investigation for the treatment of MS. Teriflunomide blocks the proliferation and functioning of activated T and B lymphocytes - which are thought to be especially damaging in MS - by selectively and reversibly inhibiting a critical mitochondrial enzyme. Slowly dividing or resting lymphocytes are unaffected by teriflunomide, leaving the immune system's response to infection uncompromised. With nine years of continuous use in a Phase II extension, teriflunomide has the longest clinical experience of any investigational oral MS therapy. In addition to the TEMSO trial, two other Phase III trials, TOWER and TENERE, are ongoing in people with RMS. A Phase III study, TOPIC, is also underway in early MS or CIS (clinically isolated syndrome). Teriflunomide is also being evaluated as an adjunct therapy to interferon- β in the Phase III TERACLES trial.

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

About Multiple Sclerosis

Today more than 2,000,000 people around the world suffer from MS, a chronic autoimmune disease that affects the central nervous system - the brain, spinal cord and optic nerves. In MS, immune cells called lymphocytes mistakenly attack myelin, the fatty "insulation" that surrounds and protects nerves, resulting in abnormal nerve transmission and MS symptoms such as fatigue, weakness, walking and balance problems, vision problems, pain, spasticity and cognitive difficulties. MS is the most common disabling neurological disease in young adults after accidents, and is two to three times more common in women than in men. MS is usually characterized by relapses followed by periods of complete or incomplete recovery. There is no typical individual with MS, as the disease is a very variable condition and the symptoms depend on which areas of the central nervous system are affected. MS symptoms can vary from time to time and can change in severity and duration, even in the same person. The vast majority of people with MS - approximately 90 percent - are initially diagnosed with a relapsing form of MS.

Magnetic resonance imaging (MRI) is a common and important tool used to help establish a diagnosis of MS and monitor the course of the disease and effects of treatment. Providing a highly sensitive, non-invasive way to image the brain, spinal cord or, other areas of the body, MRI has made it possible to visualize and understand a great deal about the underlying pathology of MS.

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. The company's areas of focus are rare genetic diseases, multiple sclerosis, cardiovascular disease, and endocrinology. Genzyme is a Sanofi company. Genzyme's press releases and other company information are available at <http://www.genzyme.com>.

Genzyme's Multiple Sclerosis business unit is responsible for the development of teriflunomide, along with the investigational MS therapy alemtuzumab.

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).

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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