News Releases

Teriflunomide Successfully Reduces Relapses and is Well Tolerated in Multiple Sclerosis Patients

- Phase III TEMSO Study Meets Goals Including Delayed Disability Progression for Teriflunomide 14mg

PARIS, Oct. 15 /CNW/ - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today the results from the two year phase III TEMSO study of teriflunomide, a novel oral disease modifier investigated for the treatment of relapsing multiple sclerosis (RMS). In this study, both doses of teriflunomide (7 and 14mg) significantly reduced annualized relapse rate (primary study endpoint) by 31% vs. placebo (p is less than or equal to 0.0005). The risk of disability progression (sustained for 12 weeks) was also significantly reduced by 30% for the 14mg dose (p=0.02) and numerically reduced by 24% for the 7mg dose (p=0.08). Both doses of teriflunomide were well tolerated with a similar number of patients reporting either treatment-emergent adverse events (TEAEs) including serious adverse events or TEAEs leading to treatment discontinuation in the treatment vs. placebo arms.

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http://www.multivu.com/players/English/46556-Sanofi-Aventis-Teriflunomide/

"We are very pleased with the successful results of the TEMSO study which are an important step forward in multiple sclerosis clinical research," said Marc Cluzel, M.D., Ph.D., Executive Vice President, Research & Development, sanofi-aventis. "These exciting results with teriflunomide represent a new real hope to delivering an oral therapy to patients who live with this serious condition and are eager for new treatment options, and more convenient product forms in-line with our sanofi-aventis commitment to multiple sclerosis."

The results of the TEMSO trial are the first study findings from a large phase III clinical development program on teriflunomide. These results were presented today during the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) congress, in Gothenburg, Sweden.

"Multiple sclerosis is a complex disease, and it often has an unpredictable and highly disabling disease course, therefore leading to important health care needs in this relatively young patient group ", said Dr. Paul O'Connor, Director of the MS Clinic at St Michael's Hospital, Toronto, Canada and principal investigator of the TEMSO study. "We were very satisfied to see how TEMSO demonstrated that teriflunomide successfully reduced relapse rate but also reduced the time to disability progression for the highest dose with a favorable safety profile for multiple sclerosis patients with relapses and emerges as a potential new first-line treatment option in this patient population."

Teriflunomide also significantly reduced the brain disease activity on a range of magnetic resonance imaging (MRI) measures including a significant reduction of the burden of disease (total lesion volume), by 39% (p=0.03) and 67% (p=0.0003) at the 7 and 14mg doses relative to placebo, respectively.

Teriflunomide was well tolerated with no major safety concerns. Adverse events occurring at a higher rate in the teriflunomide groups were diarrhea, nausea, alanine transferase increases that were mainly mild and asymptomatic with no dose effect and mild hair thinning and hair loss which rarely led to treatment discontinuation. No serious opportunistic infections occurred in patients treated with teriflunomide.

In addition to the TEMSO results, data on long-term safety of RMS patients, from eight years of follow-up of the open-label extension of a phase II study were also presented at the ECTRIMS congress. These data showed that teriflunomide was well tolerated during eight years of continuous use with a safety profile consistent with that reported during the first 36 double-blind phase weeks of the study.

About Teriflunomide

Teriflunomide is a new disease modifying drug being investigated for the treatment of multiple sclerosis with a comprehensive clinical development program which has been launched in monotherapy. First Phase II study results of the safety and efficacy of teriflunomide monotherapy in MS were published in Neurology in 2006. In addition to the TEMSO trial, two other Phase III trials, TOWER and TENERE, are ongoing in RMS patients. A Phase III study, TOPIC, is also underway in early MS or CIS (Clinically isolated syndrome). Teriflunomide has also been evaluated as an adjunct therapy to either interferon beta or glatiramer acetate in two Phase II studies. Results of these studies were presented earlier this year during the American Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) and American Academy of Neurology (AAN) meetings respectively. Phase II studies with teriflunomide (7 and 14mg) in adjunct with IFNbeta demonstrated an improvement in MRI outcomes, with a consistent safety profile in patients treated with the adjunct therapy compared to patients treated with IFNbeta and receiving placebo. In the other Phase II study, teriflunomide in adjunct to glatiramer acetate (GA) was well-tolerated compared to patients receiving GA and placebo and showed a numerical trend for the reduction in

number and volume of gadolinium enhancing T-1 brain MRI lesions in the adjunct arm compared to the placebo with GA arm.

About the TEMSO Study

TEMSO is a 2-year randomized, double-blind, placebo-controlled multinational study including 1,088 RMS patients aged 18-55 years from 21 countries, with an Expanded Disability Status Scale (EDSS) is less than or equal to 5.5 and at least one relapse in the previous year or at least 2 relapses in the preceding 2 years. Patients were randomized to placebo or teriflunomide, 7 or 14mg, once daily and followed for 108 weeks. The primary endpoint was annualized relapse rate defined as the number of confirmed relapses per patient-year. The key secondary endpoint was the time to sustained disability progression measured by the EDSS. Safety and tolerability evaluations were based on treatment emergent adverse events, physical examinations, vital signs and laboratory investigations.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, unpredictable and progressively disabling disease with a substantial burden on patients. MS patients typically are diagnosed at a young age and they face a lifetime of uncertainty with gradually declining health. Today, over two million people around the world suffer from MS. MS is the result of damage to myelin, a protective sheath surrounding nerve fibres of the central nervous system. When myelin is damaged, this interferes with messages between the brain and other parts of the body. Multiple sclerosis is a very variable condition and the symptoms depend on which areas of the central nervous system have been affected. There is no definite pattern to MS and everyone with MS has a different set of symptoms, which vary from time to time and can change in severity and duration, even in the same person. Management of MS is complex; early intervention in the pathological process is recommended in order to delay disease progression or at least, slow it down. A complex support system is required for the care of MS patients, including health and social services, as well as various healthcare professionals. Although there is no known cure for multiple sclerosis, several therapies are proven to be helpful but there remains an unmet need for new oral therapies with proven efficacy and good tolerability as well as long term safety.

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis 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-aventis' 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-aventis, 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 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-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2009. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

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