

## **Teriflunomide Significantly Reduced Annualized Relapse Rate and was Well Tolerated in MS Patients**

- First Results From the TEMSO Phase III Trial to be Presented During the ECTRIMS Congress in October 2010

PARIS, Aug. 30 /CNW/ - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that the investigational once-daily oral drug teriflunomide significantly reduced annualized relapse rate (ARR) at 2 years versus placebo in patients with relapsing multiple sclerosis (RMS), thus achieving the primary endpoint in the TEMSO phase III trial. Both the 7mg and 14mg doses of teriflunomide were well tolerated with a similar number of patients reporting either treatment-emergent adverse events (TEAEs) or TEAEs leading to treatment discontinuation in the treatment arms versus placebo.

Effects on other clinical and MRI related outcomes further support the primary outcome. The safety profile was in line with previous clinical experience.

The TEMSO trial is the first study of a large phase III clinical development program to produce results on teriflunomide as monotherapy. Study findings from TEMSO will be presented during the platform presentation scheduled for October 15, 2010, starting at 9:15 a.m. CET at the 26th Annual Meeting of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Gothenburg, Sweden. The TEMSO study results are embargoed until this oral presentation.

### **About Teriflunomide**

Teriflunomide is a new oral disease modifier for RMS that blocks de novo pyrimidine synthesis thus reducing T- and B-cells proliferation with no cytotoxicity. A comprehensive clinical development program for teriflunomide 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. A Phase III study, TOPIC, is also underway in early MS or Clinically Isolated Syndrome (CIS). Teriflunomide has also been evaluated as an adjunct therapy to either interferon 1-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 meeting (ACTRIMS) congress, and the American Academy of Neurology (AAN) meeting respectively. Phase II studies with teriflunomide (7mg and 14mg) in adjunct with interferon 1-beta demonstrated an improvement in outcomes, with a consistent safety profile in patients treated with the adjunct treatment compared with patients treated with IFN-beta 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. Although there was a numerical trend for the reduction in number and volume of gadolinium enhancing T-1 brain MRI lesions in the adjunct arm compared to placebo with GA, the relative effect was not as robust as that observed for teriflunomide with IFN-beta.

### **About TEMSO Study**

TEMSO is a 2-year randomized, double-blind, placebo controlled study including 1088 RMS patients worldwide, aged 18-55 years, with an Expanded Disability Status Scale (EDSS) (less than or equal to) 5.5 and at least one relapse over the previous year or at least 2 relapses over the preceding 2 years. Patients were randomized to placebo or teriflunomide, 7mg or 14mg, once daily. The primary endpoint was annualized relapse rate defined as the number of confirmed relapses per patients-year. The key secondary endpoint was the time to disability progression measured by 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. Patients with MS 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 an acceptable benefit/risk profile.

#### 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.

For further information: Media contact: Philippe BARQUET, Tel: +33(0)6-70-48-61-28, Email: [philippe.barquet@sanofi-aventis.com](mailto:philippe.barquet@sanofi-aventis.com)

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