

## **Sanofi-aventis Initiates Phase III Study with Teriflunomide as Adjunct Therapy with Interferon Beta to Further Explore Clinical Benefits in Multiple Sclerosis**

***-TERACLES is the first Phase III study of an oral drug as an add-on to standard therapy in relapsing multiple sclerosis -***

**Paris, France – October 26 , 2010** – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today the initiation of a multinational Phase III study evaluating the efficacy and safety of two doses of once daily teriflunomide (7mg or 14mg) versus placebo in patients with relapsing multiple sclerosis (RMS) treated with interferon beta (IFN  $\beta$ ). Teriflunomide is a novel oral disease modifier developed by sanofi-aventis which is being investigated in a large Phase III clinical development program. It includes studies of teriflunomide in monotherapy for the treatment of RMS and in clinically isolated syndrome as well as adjunct therapy.

*“Initiation of the TERACLES study is a tremendous milestone as it is the first ever Phase III study of an oral drug in adjunct therapy to be launched in multiple sclerosis,”* said Marc Cluzel, M.D., Ph.D., Executive Vice President, Research & Development, sanofi-aventis. *“We are confident that teriflunomide is an excellent candidate for assessing innovative adjunct therapy in multiple sclerosis considering the positive effect observed when it was used in adjunct with interferon beta in the Phase II study.”*

Specifically, the TERACLES study will evaluate whether once daily oral teriflunomide 14 or 7mg, in patients treated for at least 6 months on a stable dose of IFN  $\beta$  prior to randomization, can reduce the annualized relapse rate (primary endpoint) compared to IFN  $\beta$  plus oral placebo tablets. The main secondary endpoints of the study are to document the disease activity measured by MRI, the time to disability progression and overall safety.

*“The purpose of the TERACLES study is to assess the clinical benefits of teriflunomide as an adjunct therapy in patients with relapsing multiple sclerosis,”* said Mark S. Freedman, HBSc, MSc, M.D., Professor of Neurology, Department of Medicine, and University of Ottawa, Ontario, Canada. *“We hope that this study will replicate the additional efficacy and safety profile we observed in the Phase II trial with teriflunomide in adjunct with interferon beta, and bring an innovative therapeutic approach to this patient population.”*

The Phase II study results presented this year during the ACTRIMS congress showed that teriflunomide in adjunct with IFN  $\beta$  significantly improved disease control (evaluated by MRI activity) beyond IFN  $\beta$  plus oral placebo at one year, with a trend towards fewer clinical relapses and with a consistent safety profile with the data from a Phase II monotherapy study.

Approximately 240 study sites in 28 countries are targeted for participation in the TERACLES study which will involve 1455 RMS patients. The first patient is expected to be enrolled before the end of this year and the trial will end once the last patient recruited has received at least 48 weeks of treatment.

## About Teriflunomide

Teriflunomide is a new chemical entity being studied in a far-reaching and ambitious clinical program including more than 3.500 patients in 36 countries. Teriflunomide has previously 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. In one of this 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  $\beta$ . Teriflunomide is also being investigated in a monotherapy clinical development program. TEMSO Phase III trial positive results have been presented during the last European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) congress and showed that teriflunomide successfully reduces annualized relapses rate (primary study endpoint) vs placebo and was well tolerated in MS patients. Two other Phase III trials, TOWER and TENERE, are also ongoing in RMS patients. A Phase III study, TOPIC, completes the clinical development in early MS or CIS (Clinically isolated syndrome).

## 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 good 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 a statement does not undertake any obligation to update or revise any forward-looking information or statements.*

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