Teriflunomide in adjunct to interferon beta significantly improved outcomes of Multiple Sclerosis patients

- One-year Phase II data presented at the 2010 ACTRIMS meeting -

Paris, France – June 5, 2010 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) reported today new one-year data from a Phase II study with teriflunomide, a novel oral disease modifier being investigated for the treatment of relapsing multiple sclerosis (RMS). Study results demonstrated an improvement in outcomes, with a consistent safety profile with the data from a previous Phase II monotherapy study, in patients treated with interferon beta (IFN-β) - a standard therapy in RMS - and receiving teriflunomide 7mg or 14mg, compared with patients treated with IFN-β and receiving oral placebo.

The findings were the subject of the leading oral presentation at the American Committee for Treatment and Research in Multiple Sclerosis meeting (ACTRIMS) in San Antonio, TX, USA. This study is part of a comprehensive clinical development program for teriflunomide both in monotherapy and in adjunct therapy in MS patients.

Although this Phase II study (n=116) was not powered to test for efficacy, patients taking 7mg or 14mg teriflunomide in adjunct to stable dose IFN-β experienced a significant relative risk reduction (86%; p=0.0005 and 82.8%; p<0.0001 respectively) in the number of gadolinium enhancing T1 (T1-Gd) lesions on brain magnetic resonance imaging compared with patients taking stable dose IFN-β with placebo. No unexpected safety findings have been showed with teriflunomide during the one-year period of the study as compared to the initial six-month period. Discontinuations due to treatment-emergent adverse events (TEAEs) were low and numerically similar in the three groups (placebo: 2; 7mg: 3; 14mg: 3).

"*These full-year exploratory study results are encouraging as they demonstrate significant improvement in disease activity based on MRI and an acceptable safety profile associated with teriflunomide when added on top of stable therapy with IFN- β,*" said Mark S. Freedman, HBSc, MSc, M.D., Professor of Neurology, Department of Medicine, University of Ottawa, Ontario, Canada. "*Adjunct therapy could fill an unmet medical need for those patients who are on interferon therapy but have some disease activity as measured by MRI or relapse rate. We hope to replicate the results in a Phase III study program.*"

A dose-dependent trend toward a relative risk reduction in the volume of brain lesions was observed with teriflunomide 7mg or 14 mg groups when used as adjunct therapy compared with placebo (72.1%; p=0.11 and 70.6%; p=0.01 respectively). There was also a dose-dependent trend to a reduction in annualized relapse rate of 32.6% (p=0.43) and 57.9% (p=0.11) in 7mg or 14mg teriflunomide adjunct groups respectively compared to IFN- β with placebo.

The most frequently reported treatment emergent adverse events were upper respiratory tract infections as a whole (placebo: 17.1%; 7mg: 16.2%; 14mg: 23.7%), mainly nasopharyngitis and sinusitis, all types of headaches (placebo: 7.3%; 7mg: 5.4%; 14mg: 18.4%), all gastrointestinal disorders (placebo: 24.4%; 7mg: 18.9%; 14mg: 31.6%). White blood cell counts decreases were numerically comparable in both

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teriflunomide and placebo treatment groups (placebo: 3; 7mg: 3; 14mg: 4) and no patients discontinued treatment due to neutropenia or infection. Hepatic TEAEs were mainly asymptomatic liver enzyme elevation; mostly alanine aminotransferase (ALT) increased, not exceeding three times the upper limit of the norm and no cases of concurrent increase of ALT and total bilirubine were reported.

About teriflunomide

Teriflunomide is a new oral disease modifier 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 (Phase III studies are ongoing) and in adjunct therapy (Phase II studies are closed). This Phase II study with once daily oral teriflunomide on top of IFN-β was a multicenter, placebo-controlled, double-blinded, randomized study, conducted in relapsing multiple sclerosis patients. The primary objective of the study was to evaluate the tolerability and safety of teriflunomide 7mg and 14mg in adjunct therapy with IFN-β. The one-year results of this study presented this year during the ACTRIMS congress complement the 24-weeks study results presented last year at the European Committee for Treatment and Research in Multiple Sclerosis congress (ECTRIMS). Results from a second Phase II study with teriflunomide in adjunct therapy with glatiramer acetate (GA) compared with matching placebo added to GA, were also presented this year during the American Academy of Neurology (AAN) meeting.

About Multiple Sclerosis

Multiple sclerosis (MS) is one of the most disabling diseases in young patients beside accidents. 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 set 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 essential in order to delay disease progression or at least, slow it down. It involves several layers of 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 effective new oral therapies are eagerly awaited.

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). For more information, please visit: www.sanofi-aventis.com.

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 does not undertake any obligation to update or revise any forward-looking information or statements.

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