Encouraging phase II results with teriflunomide in patients with relapsing multiple sclerosis

- Safety and efficacy data presented at the 2009 ECTRIMS -

Paris, France – September 11, 2009 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today the results of a phase II study with teriflunomide a novel orally available immunomodulatory therapy for multiple sclerosis (MS). In a 24-week study, teriflunomide when added to background stable therapy with interferon (IFN-beta) showed acceptable tolerance and safety (primary endpoints) and showed significant improvements of the disease as measured by magnetic resonance imaging (MRI) with the two doses tested versus placebo. These results were presented today at the 25th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS).Teriflunomide is currently being explored in a phase III program for relapsing forms of MS.

With regard to efficacy, disease control as assessed through MRI activity measures, improved beyond that achieved with IFN-beta therapy alone as shown by reductions in cerebral inflammatory lesions compared to placebo (56% with 7 mg, 81% at 14 mg, both $p<0.001$). Only few clinical relapses were reported in each group over the 24-week treatment period.

"This exploratory study shows that teriflunomide can be administered on top of stable therapy with interferon with an acceptable safety and tolerability profile" said Mark S. Freedman, HBSc, MSc, MD - Professor of Neurology, Department of Medicine, University of Ottawa, Ontario, Canada. *"Although the study was not powered to test for efficacy, we were pleased to see a significant additional effect of teriflunomide over interferon-beta alone in reducing MRI activity measures. These results encourage longer term studies to establish the clinical benefit of combination treatment in this disease where effective new therapies are eagerly awaited."*

Approximately 90% of patients completed the 24-week treatment period in each group. Treatment was prematurely discontinued for treatment-emergent adverse events (TEAEs) in one patient in each group. The proportion of patients with TEAEs due to increased alanine aminotransferases (ALT) was higher on 14 mg (28.9%) than on 7 mg (13.5%) or placebo (12.2%). Among them, the proportion of patients with ALT greater than 3xULN (upper limit of normal) was low (4.8% in placebo; 0% in 7 mg; 5.2% in 14 mg) with one treatment discontinuation from placebo and one from 14 mg. No cases had associated bilirubin increase. The proportion of patients with TEAEs potentially related to immunosuppression (including white blood cell counts, infections and infestations) was higher in the teriflunomide groups (placebo: 32%, 7 mg: 49%, 14 mg: 47%). Among these events upper respiratory tract infections (nasopharyngitis, sinusitis) appeared to be more frequent at 14 mg (23.7%) than placebo (14.6%) and 7 mg (10.8%). None of these events led to treatment discontinuation. Overall the safety profile was similar to what has been previously reported for teriflunomide. *

Sanofi-aventis www.sanofi-aventis.com
Media Relations: Tél. : (+) 33 1 53 77 44 50 - E-mail : MR@sanofi-aventis.com
Investor Relations : Tél. : (+) 33 1 53 77 45 45 - E-mail : IR@sanofi-aventis.com

Teriflunomide is a selective inhibitor of de novo pyrimidine synthesis which modulates the proliferation of T- and B-lymphocytes, and has antiproliferative and anti-inflammatory properties. In this 24-week double blind, placebo-controlled, randomized, 3-arm multinational phase II clinical study conducted in 116 patients with relapsing-remitting MS, patients received, one of the two study doses (7 mg or 14 mg once daily) or placebo on top of stable background therapy with IFN- beta. The study primary endpoints were the tolerability and safety of 7 mg and 14 mg doses of teriflunomide administered orally once daily. Efficacy was assessed based on MRI activity measures and patients' relapses were recorded over the course of the study.

*O' Connor, Neurology, 2006

About teriflunomide

Teriflunomide is a novel orally available immunomodulatory therapy in multiple sclerosis (MS), currently under investigation. It is a selective inhibitor of de novo pyrimidine synthesis which exerts a cytostatic effect on proliferating T- and B-lymphocytes in the periphery, and thus has antiproliferative and anti-inflammatory properties.
A proof-of-concept clinical trial in patients with relapsing forms of MS has demonstrated that teriflunomide monotherapy significantly reduces MRI activity and improves clinical endpoints, effects that are maintained with long term treatment. Phase III for monotherapy is currently ongoing.
In addition, the effects of early intervention with teriflunomide in patients with a clinically isolated syndrome consistent with demyelination are also being evaluated thus making the extensive development programme of teriflunomide (~3,000 patients) one of the widest of any of the new oral disease-modifying agents; it is hoped it will bring a new treatment both effective and with identified and manageable risks to the market.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, progressive, degenerative neurological disease, mediated by immune system dysregulation, culminating in demyelination and axonal damage within the central nervous system. MS imposes a significant burden on patients, and is one of the most common neurological diseases in young adults, and the leading cause of non-traumatic disability in young and middle-aged adults. An estimated two million people are living with MS worldwide, and with global population growth, its prevalence is expected to increase. Although significant progress in MS treatment has been made over the last two decades, most notably with the emergence of disease-modifying therapies - all administered parenterally, not all patients have full disease control and the use of additional therapy in conjunction with IFN-β or glatiramer acetate might offer further benefit to patients

About MRI

The magnetic resonance imaging (MRI) is a complementary examination currently used for the diagnosis of multiple sclerosis in association to clinical examination. It also allows to measure the activity of the disease (activity of the lesions) and contributes to the assessment of the treatments in the clinical studies.

About ECTRIMS

The European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) is a representative European organization that facilitates communication and creates synergies among clinicians and scientists to promote and enhance research and improve clinical outcomes in multiple sclerosis

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 product development, product potential projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, 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 EMEA, 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 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, 2008. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

Media contact :

Richard Vento
Tel: +33 1 53 77 43 18
Mobile: + 33 6 78 79 93 26
Email: richard.vento@sanofi-aventis.com