

Multaq[®] (dronedarone) Recommended for Approval in the European Union

Paris, France – September 25, 2009 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending to grant a marketing authorization in the European Union for Multaq[®] (dronedarone – 400mg Tablets).

The CHMP has recommended the approval of Multaq[®] in adult clinically stable patients with history of, or current non-permanent atrial fibrillation (AF) to prevent recurrence of AF or to lower ventricular rate.

In the Summary of Positive Opinion, the CHMP has acknowledged that dronedarone has been shown, in addition to its rhythm and rate controlling properties, to decrease the risk of atrial fibrillation-related hospitalisations.

The positive opinion from the CHMP needs now to be ratified by the European Commission.

“Sanofi-aventis welcomes the positive CHMP recommendation for the approval of Multaq[®] in the European Union” said Jean-Pierre Lehner, Chief Medical Officer, sanofi-aventis. *“This decision brings new hope to people whose lives are impacted by the potential cardiovascular complications of atrial fibrillation. We do think that Multaq[®] will contribute to fulfill significant unmet medical needs for the patients”.*

The CHMP positive opinion is based on the submission of a comprehensive clinical data package including seven international, multi-center, randomized clinical trials involving more than 7000 patients and including the landmark ATHENA trial.

The ATHENA trial involved 4,628 patients with Atrial Fibrillation / Atrial Flutter or a recent history of these conditions and showed that Multaq[®] (dronedarone) in addition to standard therapy, reduced the combined endpoint of cardiovascular hospitalization or death from any cause by 24% ($p < 0.001$) when compared to placebo, meeting the study's primary endpoint. Reported significant adverse events in the Multaq[®] arm included diarrhea, nausea, bradycardia, QT-interval prolongation and cutaneous rash.

The incidence of atrial fibrillation is growing worldwide in relation to aging populations. It is emerging as a public health concern and affects about 4.5 million people and represents one-third of hospitalizations for arrhythmia in the European Union¹. Atrial fibrillation leads to potential life-threatening complications. AF increases the risk of stroke up to five-fold², worsens the prognosis of patients with cardiovascular risk factors³, and doubles the risk of mortality⁴ with significant burden on patients, health care providers and payers.

Multaq[®] has recently received approval from the U.S. Food and Drug Administration (FDA), Health Canada and Swissmedic (Swiss Health Authority).

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.

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FOR MORE INFORMATION PLEASE VISIT:

Dronedarone press office: <http://www.dronedarone-atrial-fibrillation-pressoffice.com>

References:

¹ Go AS, Hylek EM, Phillips KA, et al. Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management and stroke prevention: the AnTicoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. JAMA 2001; 285:2370–5.

² Lloyd-Jones et al. Lifetime Risk for Development of Atrial Fibrillation: The Framingham Heart Study. Circulation. 2004; 110:1042-1046.

³ Fuster V et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation. European Heart Journal (2006) 27, 1979-2030.

⁴ Benjamin EJ, Wolf PA, D'Agostino RB, Silbershatz H, Kannel WB, Levy D. Impact of atrial fibrillation on the risk of death: the Framingham Heart Study. Circulation 1998 Sep 8; 98(10):946-52..