Further Analysis From ATHENA Study Showed that Multaq® (dronedarone) Reduced the Risk of Stroke in Patients With Atrial Fibrillation

- This analysis showed that Multaq® (dronedarone) decreased the risk of stroke by 34% in patients with atrial fibrillation or atrial flutter already adequately treated by antithrombotic therapy -

Paris, France, September 3, 2008 - The results of a post-hoc analysis of the data from the ATHENA study were presented today at the clinical trial update session of the European Society of Cardiology congress 2008, in Munich, Germany. Previous results from the landmark ATHENA study have shown that the investigational medicine Multaq® (dronedarone) on top of standard therapy decreased the combined primary endpoint of the risk of cardiovascular hospitalisations or death from any cause by a statistically significant 24% (p=0.00000002) as compared to placebo.

The ATHENA stroke post-hoc analysis on non-pre-specified secondary endpoints showed that Multaq® decreased the risk of stroke (ischemic or haemorrhagic) compared to placebo by 34% (46 vs 70 stroke events respectively; p=0.027) in atrial fibrillation / atrial flutter patients adequately treated by standard therapy including antithrombotics.

The significant reduction in stroke risk with Multaq® was incremental to background anti-thrombotic therapy like oral anticoagulants and / or anti-platelet agents. Similar to the ATHENA primary endpoint of CV hospitalizations or death, this effect appeared early and was maintained during the study follow-up (12 to 30 months).

"ATHENA is a landmark trial that will lead to a paradigm shift in the management of atrial fibrillation as it is the first time that an anti-arrhythmic drug has shown a significant impact on cardiovascular outcomes. As stroke is one of the leading complications of atrial fibrillation, and a major cause of death and long-term disability, these new results demonstrate the unique profile of Multaq® *beyond its pure rhythm and rate-controlling effects,"* said Professor Stuart Connolly, Mc Master University, Department of Cardiology, Hamilton Canada, co-principal investigator of the ATHENA study.

The most frequently reported adverse events of Multaq® vs. placebo in the ATHENA trial as seen in the pre-specified safety analysis, were gastrointestinal effects (26% vs. 22%), skin disorders (10% vs. 8%, mainly rash) and a mild increase in blood creatinine (4.7% vs. 1%) due to inhibition of tubular secretion of creatinine in the kidneys. The mechanism of blood creatinine increase was well defined in a separate study of healthy volunteers. In the ATHENA trial, compared to placebo, Multaq® showed a low risk of pro-arrhythmia and no excess of hospitalisations for congestive heart failure. There was a similar rate of study drug discontinuation between the 2 study groups.

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About Atrial Fibrillation / Flutter and Stroke
Atrial Fibrillation (AF) is the most common cardiac arrhythmia in clinical practice and is one of the most important independent risk factors for stroke. Stroke is a major public health problem because this acute event often causes permanent neurological disabilities and death. Atrial fibrillation increases the risk of stroke by up to 5 times. It also is responsible for 15-20% of all strokes, which if caused by AF, are 2.2 times more likely to leave patients bedridden.

Atrial fibrillation is a major cause of hospitalisation and mortality and affects about 2.5 million people in the USA and 4.5 million people in the European Union. The Atrial Fibrillation Foundation expects the number of patients with AF to double in the next 20 years. Without appropriate management, atrial fibrillation can lead to serious complications, such as stroke and congestive heart failure.

About the ATHENA Study
The landmark ATHENA, study is the only double-blind, anti-arrhythmic, morbidity-mortality study in patients with atrial fibrillation. It was conducted in more than 550 sites in 37 countries and enrolled a total of 4,628 patients.

The patients studied in ATHENA were either 75 years of age or older (with or without cardiovascular risk factor) or above 70 years of age with at least one additional cardiovascular risk factor (hypertension, diabetes, previous cerebrovascular event, left atrium size greater than 50 mm or left ventricular ejection fraction lower than 40%). Patients were randomized to receive Multaq® 400 mg BID or placebo, with a maximum follow-up of 30 months.

The ATHENA study objectives were to show a potential benefit of Multaq® on the primary composite endpoint of all-cause mortality combined with cardiovascular hospitalization as compared to placebo. The pre-specified secondary endpoints were death from any cause, cardiovascular death and hospitalisations for cardiovascular reasons. The pre-specified safety endpoint was the incidence of treatment emergent adverse events (between first study drug intake and last study drug intake plus 10 days) including: all adverse events, serious adverse events, adverse events leading to study drug discontinuation.

The ATHENA stroke post-hoc analysis on a non-pre-specified secondary endpoint was conducted in order to confirm the consistent benefit of Multaq® in atrial fibrillation or atrial flutter patients in reducing major cardiovascular complications like stroke, which is a leading cause of cardiovascular hospitalization or death in this patient population.

About Multaq® (dronedarone)
Multaq® is an investigational treatment and the only anti-arrhythmic drug (AAD) to have shown a significant reduction in morbidity and mortality in atrial fibrillation /atrial flutter patients with a favourable safety profile as evidenced by a low incidence of pro-arrhythmia (including torsades de pointes) and extra-cardiac organ toxicity.
Multaq®, discovered and developed by sanofi-aventis, has been studied in a clinical development program including more than 7,000 patients. Multaq® is one of the major therapeutic innovations in the field of atrial fibrillation in the last twenty years.
Multaq® has been granted a priority review by the U.S. Food and Drug Administration (FDA) and a registration dossier is also under regulatory review by the European Medicines Agency (EMEA).

About sanofi-aventis
Sanofi-aventis, a leading global pharmaceutical company, contributes to improving life by providing a broad offering of medicines, vaccines, and integrated healthcare solutions adapted to local needs and means.

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, 2007. 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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