

New England Journal of Medicine publishes results from the landmark ATHENA trial with Multaq[®] (dronedarone) in Atrial Fibrillation

-Multaq[®] (dronedarone) significantly reduced the risk of cardiovascular hospitalization or death by 24 percent in patients with atrial fibrillation-

Paris, France – February 11, 2009 - Sanofi-aventis (Paris Bourse: EURONEXT: SAN; and New York: NYSE: SNY) announced today that the ATHENA trial was published in the New England Journal of Medicine. The trial showed that Multaq[®] (dronedarone), in addition to standard therapy, significantly reduced the risk of first cardiovascular hospitalization or death by 24 percent (31.9% vs. 39.4%, $p < 0.001$) in patients with atrial fibrillation (AF)/atrial flutter (AFL) or a recent history of these conditions.

Atrial fibrillation is the leading cause of hospitalization for arrhythmia in the US¹ and represents one-third of hospitalizations for arrhythmia in Europe². Hospitalization due to AF has increased dramatically (two-to-three fold) in recent years in the US¹. Atrial fibrillation is a complex disease that increases the risk of stroke up to five-fold³, worsens the prognosis of patients with cardiovascular risk factors⁴ and that doubles the risk of mortality⁵.

The authors' findings, as reported in the New England Journal of Medicine, showed a significant decrease in the risk of cardiovascular death by 29% ($p = 0.03$) in patients with AF. Multaq significantly decreased the risk of arrhythmic death by 45% ($p = 0.01$) and there were numerically fewer deaths (16%) from any cause in the dronedarone group compared to placebo ($p = 0.18$). First cardiovascular hospitalization was reduced by 26% ($p < 0.001$) in the dronedarone group.

"The ATHENA trial is the first trial to show a reduction in the incidence of cardiovascular hospitalization or death in patients taking an anti-arrhythmic drug for atrial fibrillation" commented Dr. Stefan H. Hohnloser J.W., Goethe University's Division of Clinical Electrophysiology, Frankfurt, Germany, principal investigator of the ATHENA study.

Reported significant adverse events in the Multaq[®] arm vs. placebo arm included diarrhea (9.7% vs. 6.2%), nausea (5.3% vs. 3.1%), bradycardia (3.5% vs. 1.2%), QT-interval prolongation (1.7% vs. 0.6%); skin disorders (10.3% vs. 7.6%) consisting mainly of rash, and an increase in blood creatinine (4.7% vs. 1.3%)*. There was no difference in permanent study drug discontinuation between Multaq[®] and placebo (30.2% vs. 30.8%).

Dr. Stuart J. Connolly, Director of the division of cardiology at McMaster University, Ontario, Canada and co-principal investigator of the ATHENA trial said *"The clinical benefits observed with dronedarone in ATHENA occurred without a significantly higher rate of thyroid or pulmonary disorders compared with placebo reported within the study period."*

* The mechanism of blood creatinine increase was well defined in a separate study of healthy volunteers and is not indicative of

About the ATHENA Study

The landmark ATHENA study is the only double-blind, antiarrhythmic study in patients with AF that assesses morbidity-mortality. The study was conducted at 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 factors) or below 75 years of age with at least one additional cardiovascular risk factor (hypertension, diabetes, previous ischemic cerebrovascular event, left atrium size greater than 50 mm or left ventricular ejection fraction lower than 40 percent). Patients with recently decompensated heart failure or in New York Heart Association (NYHA) class IV were excluded. Patients were randomized to receive dronedarone 400 mg BID or placebo, with a mean follow-up of 21 months.

The ATHENA study objectives were designed to show a potential benefit of dronedarone on the primary composite endpoint of all-cause mortality combined with cardiovascular hospitalization compared with placebo. The pre-specified secondary endpoints were death from any cause, cardiovascular death and hospitalization 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 and adverse events leading to study drug discontinuation.

About Atrial Fibrillation

AF is a common heart arrhythmia in which the upper chambers of the heart beat in an uncoordinated and disorganized fashion, which can cause palpitations, shortness of breath and fatigue. AF currently represents a major economic burden for society. Seventy percent of the annual cost of AF management in Europe is driven by in-patient care and interventional procedures. Hospitalizations for AF have increased dramatically (two-to-three-fold) in recent years. AF hospitalizations now represent a third of all hospitalizations for arrhythmia and mortality in the US and Europe. AF affects nearly 7 million people in the European Union and the United States.

The condition is increasingly frequent with advancing age and is often caused by age-related changes in the heart or as a result of cardiovascular disease. AF increases the risk of stroke up to five-fold and heart failure two-to-three-fold. AF also doubles the risk of mortality.

Without appropriate management, AF can lead to serious complications such as stroke and congestive heart failure. In addition to preventing stroke and reducing the burden of the disease, successful management of AF should also aim at further reducing cardiovascular morbidity and mortality.

The goals of treatment for patients with AF are related to managing the arrhythmia itself and to the prevention of thromboembolism. AF may be treated with medications that either slow the heart rate or revert the heart rhythm back to normal sinus rhythm.

About dronedarone (Multaq®)

Multaq® (dronedarone) is an investigational treatment and the only antiarrhythmic drug to have shown a significant reduction in cardiovascular hospitalization or death in patients with AF/AFL. Multaq®, discovered and developed by sanofi-aventis, has been studied in a clinical development program including more than 6,200 patients. Multaq® is one of the major therapeutic innovations in atrial fibrillation for 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 (EMA).

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, 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.

- (1) Singh SN et al. J Am Coll Cardiol. 2006;48:721-730
- (2) Fuster V et al. ACC/AHA/ESC Guidelines. European Heart Journal 2006;27:1979–2030
- (3) Wolf et al. Stroke. 1991;22:983-988.
- (4) Wachtell K et al. J Am Coll Cardiol. 2005;45:712-719.
- (5) Benjamin EJ et al. Circulation. 1998;98:946-952.

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