

Landmark ATHENA Study Findings With Multaq® (dronedarone) Show 24% Reduction in Cardiovascular Hospitalisation or Death in Patients With Atrial Fibrillation

Paris, France - May 15, 2008 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that findings from the landmark ATHENA study showed that Multaq® (dronedarone), a potential therapy for the treatment of patients with atrial fibrillation or atrial flutter, decreased the risk of cardiovascular hospitalisations or death from any cause by a statistically significant 24% ($p=0.00000002$), meeting the study's primary endpoint. The ATHENA results will be presented at the late breaking clinical trial session of Heart Rhythm 2008, the Heart Rhythm Society's 29th Annual Scientific Sessions in San Francisco, USA.

For the first time in twenty years of clinical drug trials in atrial fibrillation, an investigational medicine, Multaq®, showed a significant decrease in the risk of cardiovascular death by 30% ($p=0.03$) on top of standard therapy, including rate control and antithrombotic drugs, in patients with atrial fibrillation or atrial flutter. Multaq® also 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 ($p=0.17$). First cardiovascular hospitalisation was reduced by 25% ($p=0.000000009$) in the dronedarone group.

"The ATHENA results have the potential to change the face of atrial fibrillation management. For atrial fibrillation patients, who together with their physicians struggle on a daily basis to manage the dramatic consequences of this complex disease, Multaq® carries hope for patients" said Marc Cluzel, sanofi-aventis Senior Vice President, R&D. "This milestone is indicative of sanofi-aventis' commitment to bringing innovative therapies to market, and of our ongoing commitment to provide patients, physicians and public health stakeholders with breakthrough medicines in those therapeutic areas where there are major healthcare needs and limited solutions".

Atrial fibrillation is a major cause of hospitalisation and mortality and affects about 2.5 million people in the United States, as well as 4.5 million people in the European Union and is emerging as a growing public health concern due to an aging population. Patients suffering from atrial fibrillation have twice the risk of death, an increased risk of stroke and cardiovascular complications, including congestive heart failure. Furthermore atrial fibrillation considerably impairs patients' lives, mainly because of their inability to perform normal daily activities due to complaints of palpitations, chest pain, dyspnoea, fatigue or light-headedness, without consideration of the cumbersome and sometime serious constraints imposed by current therapies of atrial fibrillation.



“In atrial fibrillation where treatment morbidity-mortality benefit still needed to be demonstrated, ATHENA is a unique trial using clinically relevant outcomes such as cardiovascular hospitalisation or death as the primary endpoint. In this regard, the trial has clearly achieved these safety and efficacy endpoints,” said Dr Stefan H. Hohnloser, J.W. from the Goethe University, Division of Clinical Electrophysiology, Frankfurt, Germany, who served as co-principal investigator of the ATHENA study. *“As a consequence, dronedarone is the first safe treatment for atrial fibrillation, which has been demonstrated to reduce cardiovascular hospitalisation or mortality in patients with AF”* he added.

The most frequently reported adverse events of Multaq® vs. placebo in the ATHENA trial were gastro-intestinal effects (26% vs. 22%), skin disorders (10% vs. 8%, mainly rash) and increased blood creatinine (4.7% vs. 1%). The mechanism of blood creatinine increase (inhibition of creatinine secretion at the renal tubular level) is well defined. 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.

“ATHENA is truly a landmark trial, that marks a paradigm change for the management of atrial fibrillation,” said Dr Christopher Cannon, a Senior Investigator in the TIMI Study Group at Brigham and Women’s Hospital, who was not involved in the study. *“Atrial fibrillation is a very common disease, and our prior treatment options have been focused only on symptom relief and a hope to not do harm, which has been the problem with prior antiarrhythmic drugs. Now, with a highly significant reduction in death or hospitalisation, as well as a 45% reduction in arrhythmic death or 30% cardiovascular death, dronedarone may become a first line treatment of atrial fibrillation”.*

ATHENA, the largest double blind randomised study in patients with atrial fibrillation, was conducted in more than 550 sites in 37 countries and enrolled a total of 4,628 patients. The landmark ATHENA trial is the first morbidity-mortality study as part of the Multaq® phase III clinical development program, which also included five other multinational clinical studies, an initial study, ANDROMEDA, conducted in patients with severe congestive heart failure and a recent decompensation, and a total of 4 international studies in atrial fibrillation: EURIDIS/ADONIS, ERATO, and the ongoing DIONYSOS trial.

Based upon this new clinical data, sanofi-aventis plans to submit a registration dossier to the European Medicines Agency (EMA), and a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) during the 3rd quarter of 2008.

About Atrial Fibrillation / Flutter

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.

AF is a condition in which the upper chambers of the heart beat in an uncoordinated and disorganised fashion, resulting in an irregular and fast heart rhythm (i.e. an irregular heartbeat). Atrial flutter is an abnormal fast heart rhythm that occurs in the atria of the heart. This rhythm occurs often in individuals with other heart conditions (e.g. pericarditis, coronary artery disease, and cardiomyopathy). Atrial flutter frequently degenerates to atrial fibrillation. However, it may persist for months to years.

When blood is not completely pumped out of the heart’s chambers, it can pool and clot. If a blood clot forms in the atria, it can exit the heart and block an artery in the brain, resulting in a stroke. Consequently, about 15 percent of all strokes result from atrial fibrillation.

The most common symptoms of atrial fibrillation include palpitations (a rapid, irregular, “flopping” movement or pounding sensation in the chest or neck), shortness of breath, dizziness and feeling of heaviness, or constriction in the chest. The disorder may even be more common than diagnosed, as patients may experience atrial fibrillation episodes that either do not cause symptoms or are not documented during their visits to the doctor.

About the ATHENA Study

The landmark ATHENA study is a randomised, placebo controlled, international multi-center study that evaluated for the first time a treatment on top of standard background therapy for the management of patients with atrial fibrillation in reducing morbidity and mortality by preventing cardiovascular hospitalisations or death from any cause. The study included 4,628 patients, which make it the largest ever outcome study of an anti-arrhythmic treatment for atrial fibrillation.

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

The atrial fibrillation or atrial flutter patients studied were either 75 years of age or over (with or without cardiovascular risk factor) or were below 75 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 percent). Patients suffering from decompensated heart failure were excluded from the study. Patients were randomised to receive Multaq® 400 mg BID or placebo, with a maximum follow-up of 30 months.

The countries which enrolled patients included: Argentina, Australia, Austria, Belgium, Canada, Chile, China, Czech Republic, Finland, Germany, Greece, Hong Kong, Hungary, India, Israel, Italy, Malaysia, Mexico, Morocco, New Zealand, Norway, Philippines, Poland, Portugal, Russia, South Africa, Singapore, South Korea, Spain, Sweden, Taiwan, Thailand, The Netherlands, Tunisia, Turkey, the UK, the US.

About Multaq® (dronedarone)

Dronedarone (brand name Multaq®) is an investigational new treatment for patients with atrial fibrillation, which has been discovered and developed by sanofi-aventis for the prevention and treatment of patients with atrial fibrillation or atrial flutter. Dronedarone is a multi-channel blocker that affects calcium, potassium and sodium channels and has anti-adrenergic properties. Dronedarone does not contain the iodine radical and did not show any evidence of thyroid or pulmonary toxicity in clinical trials.

About sanofi-aventis in Cardiology and Thrombosis

Sanofi-aventis' unmatched experience in the treatment of millions of patients suffering from cardiovascular disease (CVD) and thrombosis has uniquely prepared us to take on the growing challenges in these domains. Today, together with academic institutions and healthcare professionals, we are a major contributor in the effort to reduce the public health burden across the broad CVD spectrum and in thrombosis.

Our comprehensive set of innovative therapeutic solutions includes antiplatelet and antithrombotic agents with Plavix® and Clexane®/Lovenox®, as well the antihypertensive agent Aprovel®/Avapro®. By listening and responding to the needs of patients and physicians, we constantly seek to improve the safety and efficacy of our products while developing new therapeutic strategies. Our dedication has already helped lay the foundations of modern cardiovascular treatment. In addition to the first-in-class ticlopidine, we pioneered treatment with amiodarone and heparins, therapies rooted in a deep legacy of research experience spanning decades.

Building on our deep foundations of experience and expertise, we are seeking improved treatment efficacy with new ultra-low-weight heparins (AVE5026), with a new reversible, long-acting anticoagulant, potentially better-suited for venous thromboembolism and atrial fibrillation (biotinylated Idraparinux). Our research into atrial fibrillation continues with ground breaking trials like ATHENA with the clinical development of dronedarone (Multaq®). We are simultaneously exploring targeted gene therapy (NV1FGF) with the aim of reducing the risk of amputation in

patients with critical ischemia of the lower limbs. As we continue to push the frontiers of cardiovascular and thrombosis therapy, we do so with the conviction that the health of patients is our total commitment and our greatest reward.

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.

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