

## **Multaq<sup>®</sup> (dronedarone) for Atrial Fibrillation or Atrial Flutter Now Available in the United States**

**- New treatment option to reduce cardiovascular hospitalization in patients with atrial fibrillation (AF) or atrial flutter (AFL) -**

**Paris, France – July 28, 2009** – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that Multaq<sup>®</sup> (dronedarone) 400 mg Tablets is now available in pharmacies in the United States. Multaq<sup>®</sup> is an anti-arrhythmic drug indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors (i.e., age >70, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter ≥50 mm or left ventricular ejection fraction [LVEF] <40%), who are in sinus rhythm or who will be cardioverted.

Multaq<sup>®</sup> was recently approved by the U.S. Food and Drug Administration on July 1, 2009.

*“Multaq<sup>®</sup> may help patients with atrial fibrillation or atrial flutter stay out of the hospital, which is an important factor in treatment that is often not addressed,”* said Gerald V. Naccarelli, M.D., Chief, Division of Cardiology, Pennsylvania State University College of Medicine. *“We welcome a new option that may help patients with Afib or Aflutter manage their disease.”*

In the landmark ATHENA trial, the efficacy and safety of Multaq<sup>®</sup> was evaluated in patients with AF/AFL or a recent history of these conditions (71% of these patients had no heart failure, 29% had NYHA class I-III stable heart failure). This trial showed that Multaq<sup>®</sup> 400 mg BID, 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. This reduction was generally consistent across study subgroups based on baseline characteristics or medications. Patients taking Multaq<sup>®</sup> had higher rates of diarrhea, nausea, bradycardia, QT-interval prolongation and cutaneous rash than patients taking placebo.

Initiation of Multaq<sup>®</sup> treatment is contraindicated in patients with severe heart failure (NYHA class IV) or NYHA Class II – III heart failure with a recent decompensation requiring hospitalization or referral to a specialized heart failure clinic. This unstable population corresponds to the population of the ANDROMEDA trial in which patients receiving dronedarone had a greater than two-fold increase in mortality compared to placebo.

To ensure the use of Multaq<sup>®</sup> in the appropriate patient population, sanofi-aventis U.S. LLC also announced the launch of mPACT (Multaq<sup>®</sup> Partnership for Appropriate Care and Treatment™), the Risk Evaluation and Mitigation Strategy (REMS). The mPACT Partnership was developed to assist healthcare professionals (HCPs) with the identification of appropriate patients and to ensure the safe use of Multaq<sup>®</sup> while minimizing risk. The risk mitigation program consists of a Communication Plan for HCPs, a medication guide for patients and post-marketing surveillance.

There are approximately 2.5 million Americans with AF and the incidence is growing worldwide in relation to the aging population. Atrial fibrillation is a complex disease that increases the risk of stroke up to five-fold, worsens the prognosis of patients with cardiovascular risk factors, and doubles the risk of mortality.

### **About Multaq® (dronedarone)**

Multaq®, discovered and developed by sanofi-aventis, has been studied in a clinical development program involving nearly 6,300 patients including more than 3,200 patients who received Multaq®. It represents one of the few new treatment options for AF/AFL patients in the last 10 years.

Multaq® is to be given twice daily as a 400 mg tablet and should be taken as one tablet with the morning and evening meals. Treatment with Multaq® can be initiated in an outpatient setting. Most common adverse reactions are diarrhea, nausea, vomiting, abdominal pain, asthenia (weakness) and cutaneous rash.

### **Important Safety Information**

Multaq® is contraindicated in patients with NYHA Class IV heart failure or NYHA Class II-III heart failure with a recent decompensation requiring hospitalization or referral to a specialized heart failure clinic. In a placebo-controlled study in patients with severe heart failure requiring recent hospitalization or referral to a specialized heart failure clinic for worsening symptoms (the ANDROMEDA study), patients given dronedarone had a greater than two-fold increase in mortality. Such patients should not be given dronedarone.

Multaq® is also contraindicated in second- or third-degree atrioventricular (AV) block or sick sinus syndrome (except when used in conjunction with a functioning pacemaker), bradycardia <50 bpm, QTc Bazett interval ≥500 ms and severe hepatic impairment.

Multaq® should not be given to patients who are or may become pregnant (Category X) or nursing.

Multaq® should not be coadministered with strong CYP 3A inhibitors or medicinal products that prolong the QT interval.

In patients with new or worsening heart failure, the suspension or discontinuation of Multaq® should be considered.

Serum creatinine levels increase by about 0.1mg/dL following Multaq® treatment initiation. The elevation has a rapid onset, reaches a plateau after 7 days and is reversible after discontinuation.

Hypokalemia and hypomagnesemia may occur with concomitant administration of potassium-depleting diuretics. Potassium levels should be maintained in the normal range pre and during administration.

**For full prescribing information, please visit: <http://products.sanofi-aventis.us/Multaq/Multaq.pdf>**

### **About Atrial Fibrillation/Atrial Flutter**

Atrial fibrillation is the most common arrhythmia, or irregular heartbeat, seen by physicians and accounts for about one-third of hospital admissions for cardiac rhythm disturbances. Hospitalization associated with AF has increased dramatically (two-to-three fold) in recent years in the U.S. Atrial flutter, another type of arrhythmia generating in the atrium, occurs less frequently, and may evolve into atrial fibrillation.

### **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 CONTACTS:**

### **Corporate**

Philippe BARQUET

Tel: +33 (0)6.70.48.61.28

Email: [philippe.barquet@sanofi-aventis.com](mailto:philippe.barquet@sanofi-aventis.com)

### **U.S.**

Marisol PERON

Tel: 908-981-6565

Mobile: 908-672-9051

Email: [marisol.peron@sanofi-aventis.com](mailto:marisol.peron@sanofi-aventis.com)

## **FOR MORE INFORMATION PLEASE VISIT:**

**MULTAQ Web site: [www.multaq.com](http://www.multaq.com)**