# Multaq® (dronedarone) for Atrial Fibrillation Now Approved in Canada

## *Second approval for Multaq® this year for management of patients with atrial fibrillation .*

**Paris, France – August 12, 2009 –** Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that Multaq® (dronedarone) 400 mg Tablets has received Health Canada approval for the treatment of patients with a history of, or current atrial fibrillation to reduce their risk of cardiovascular hospitalization due to this condition. This is the second major approval for Multaq® this year, following the approval on July 1, 2009 by the US Food and Drug Administration.

*"Multaq® may help patients with atrial fibrillation stay out of the hospital",* said Dr. Jean-Pierre Lehner, Chief Medical Officer, sanofi-aventis. *"We, as a company are pleased that Health Canada has approved Multaq® as a new treatment option that may help patients with atrial fibrillation manage their condition and may overall help reduce the burden of the disease ".*

In the landmark ATHENA trial, the efficacy and safety of Multaq® was evaluated in patients with atrial fibrillation / atrial flutter (AF / AFL) or a recent history of these conditions (71% of these patients had no heart failure, 29% were in NYHA class I-III with stable heart failure). This trial showed that Multaq® 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 in 4,628 patients followed for up to 30 months (median 22 months), meeting the study's primary endpoint.

Initiation of Multaq® is contraindicated in patients with severe congestive heart failure (classified as Stage IV by the NYHA or New York Heart Association) and other unstable hemodynamic conditions. Multaq® should be used with caution in patients with moderate congestive heart failure (NYHA Stage III).

There are approximately 250,000 Canadians with AF and the incidence is growing in relation to the aging population. Atrial fibrillation affects 2.5 million people in the United States and 4.5 million people in the European Union. 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.



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## 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 20 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.

Multaq® is contraindicated in patients with severe congestive heart failure (classified as Stage IV by the NYHA or New York Heart Association) and other unstable hemodynamic (cardiovascular) conditions, and should be used with caution in patients with moderate congestive heart failure (NYHA Stage III). Full prescribing information is contained in the product monograph.

## About Atrial Fibrillation / Atrial Flutter

Atrial fibrillation (AF) 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 atrial fibrillation has increased dramatically (two-to-three fold) in recent years. 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.*

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**For more information please visit:** http://www.dronedarone-atrial-fibrillation-pressoffice.com