DIONYSOS Study Results Showed the Respective Profiles of Dronedarone and Amiodarone

Paris, France – December 23, 2008 – Sanofi-aventis (Paris Bourse: EURONEXT: SAN; and New York: NYSE: SNY) today reported the results of the DIONYSOS trial, evaluating the efficacy and safety of dronedarone versus amiodarone for the maintenance of sinus rhythm in 504 patients with persistent Atrial Fibrillation (AF) for a short treatment duration (mean follow up of 7 months). Unsurprisingly, dronedarone showed a decrease of safety events vs. amiodarone but more occurrences of the composite primary endpoint (AF recurrence or premature drug discontinuation for intolerance or lack of efficacy).

There were 184 patients (73.9%) who reached the primary endpoint in the dronedarone arm as compared to 141 (55.3%) in the amiodarone arm ($p<0.001$). In the primary endpoint, atrial fibrillation after electrical cardioversion occurred in 36.5% of patients in the dronedarone arm vs. 24.3 % of patients in the amiodarone arm. Patients on amiodarone tended to experience more premature drug discontinuation (34 vs. 26) than patients on dronedarone.

The DIONYSOS trial also showed a decrease of 20% favouring dronedarone vs. amiodarone (83 vs. 107, $p=0.1291$) in the predefined main safety endpoint. The predefined main safety endpoint included thyroid, hepatic, pulmonary, neurological, skin, ocular, and gastrointestinal adverse events as well as premature study drug discontinuation due to any adverse event. In the dronedarone arm less thyroid events (2 vs. 15), neurological events (3 vs. 17) and premature study drug discontinuation due to any adverse events (13 vs 28) was observed. In contrast, gastrointestinal events (diarrhea, vomiting, nausea) were more frequent in the dronedarone arm (32 vs 13), consistent with previously reported studies.

When excluding GI side effects from the main safety endpoint, as also predefined in the protocol, there was a statistically significant decrease of 39% favouring dronedarone (61 vs. 99 / $p=0.0021$). Less bradycardia (8 vs. 22) and less pronounced QTc prolongation (27 vs. 52) was seen in the dronedarone arm than the amiodarone arm and no torsades de pointes were reported in the study.

"These results are as expected. Amiodarone – more effective on ECG atrial fibrillation recurrence but at high cost of organ toxicity over the long term – should remain the antiarrhythmic treatment of last resort in all patients other than those with severe heart failure." said Pr John Camm, St George's University of London.

While the DIONYSOS study was not designed to assess cardiovascular morbidity or mortality which was evaluated with long term treatment with dronedarone in the landmark ATHENA trial, there were less deaths reported in the dronedarone arm than in the amiodarone arm during the treatment period (2 vs 5).

The DIONYSOS study detailed results will be submitted to regulatory authorities, as planned. Detailed results will also be presented in a scientific congress in 2009.

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About dronedarone (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 AF/AFL patients with a favourable safety profile as evidenced by a low incidence of pro-arrhythmia (including torsades de pointes) and extra-cardiac organ toxicity. Dronedarone, discovered and developed by sanofi-aventis, has been studied in a clinical development program including more than 6,200 patients. Dronedarone is one of the major therapeutic innovations in atrial fibrillation for the last twenty years. Dronedarone (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 the DIONYSOS Study

The DIONYSOS trial is a short term, randomized double blind parallel group study comparing the efficacy and safety of dronedarone (400mg BID) versus amiodarone (600mg loading dose daily for 28 days, then 200mg daily thereafter) in 504 patients with documented atrial fibrillation for more than 72 hours for whom cardioversion and antiarrhythmic treatment were indicated in the opinion of the investigator and receiving anticoagulants.
The primary endpoint was defined as ECG-documented atrial fibrillation recurrence or premature study drug discontinuation for intolerance or lack of efficacy.
A Main Safety Endpoint (MSE) including predefined thyroid, hepatic, pulmonary, neurological, skin, ocular and gastrointestinal adverse events was defined to allow the comparison of the overall safety of the 2 agents. An analysis of the individual components of the MSE was pre-specified as well as an analysis excluding the gastrointestinal component to help a clinically meaningful interpretation of the overall results.

About the ATHENA Study

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

Previous results from the landmark ATHENA study have shown that dronedarone on top of standard therapy decreased the combined primary endpoint of cardiovascular hospitalization or death from any cause by a statistically significant 24 percent ($p<0.001$) as compared to placebo and reduced the risk of cardiovascular hospitalization by 25 percent ($p<0.001$). These results were achieved with a favorable safety profile.

The patients studied in ATHENA were either 75 years of age or older (with or without cardiovascular risk factor) either 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 with decompensated heart failure (NYHA class IV) were excluded. Patients were randomized to receive dronedarone 400 mg BID or placebo, with a maximum follow-up of 30 months.

The ATHENA study objectives were to show a potential benefit of dronedarone 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 hospitalisation 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.

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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