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Press Release

The New England Journal of Medicine Publishes EURIDIS/ADONIS Study Results Showing Dronedarone Maintained Sinus Rhythm in Patients with Atrial Fibrillation or Flutter With No Observed Pro-Arrhythmia

Paris, France (September 5, 2007) -- Sanofi-aventis announced the publication of two international trials – EURIDIS and ADONIS – which demonstrated that dronedarone (MULTAQ™), a new anti-arrhythmic agent in late stage development, is significantly more effective than placebo in maintaining sinus rhythm while not promoting pro-arrhythmias or organ toxicity (pulmonary, thyroid, liver) in patients with atrial fibrillation (AF) and atrial flutter (AFL).

AF, the most common type of irregular heart beat worldwide, is a condition in which the upper chamber of the heart beats in an uncoordinated and disorganized fashion, resulting in a very irregular and fast heart rhythm, which can potentially lead to serious cardiovascular complications. The disease affects close to one percent of the population which equates to around six million people in Europe and the US. This estimate is forecasted to increase to more than 5.6 million in the U.S. by 2050, largely due to the ageing population. AF is increasingly recognized as a progressive cardiovascular disease associated with increased morbidity and mortality.[1]

EURIDIS **(EUR**opean trial **I**n atrial fibrillation patients receiving **D**ronedarone for the ma**I**ntenance of **S**inus rhythm**)** and ADONIS (**A**merican-Australian-African trial with **D**ronedar**ON**e **I**n atrial fibrillation patients for the maintenance of **S**inus rhythm), have the same methodologies and evaluated the ability of dronedarone to maintain sinus rhythm in patients with AF and AFL.

In the EURIDIS and ADONIS trials, the median times to arrhythmia recurrence were significantly longer for dronedarone than placebo for the primary endpoint. For the EURIDIS trial, 96 days versus 41 days (p=0,014) and for the ADONIS trial, 158 days versus 59 days (p=0,002).

In the two trials, at 12 months, significantly fewer patients experienced an AF/AFL recurrence in the dronedarone group compared to the placebo groups. For the EURIDIS trial, 67.1 percent versus 77.5 percent (p=0,014) and for the ADONIS trial, 61.1 percent versus 72.8 percent (p=0,002).

“We are very pleased that these two large studies were positive and consistent in showing that dronedarone significantly reduced the recurrence of atrial fibrillation and flutter compared to placebo,” says Bramah Singh, M.D., VA Medical Center West LA, David Geffen School of Medicine, University of California Los Angeles, and lead investigator of the trials.

In both studies, dronedarone also significantly reduced the ventricular rate during arrhythmia recurrence, a secondary endpoint. This therapeutic effect is also referred to as rate control, which consists of reducing the heart rate.

“Rate control is a very interesting feature of dronedarone and compliments the anti-arrhythmic effects of the drug‘’ says Dr. Singh. “Rate control has been established to reduce symptoms. ”

A post-hoc analysis also showed that in the combined studies, dronedarone significantly reduced the rate of the combined end point of hospitalization or death compared to placebo. This important finding is being prospectively explored in an ongoing morbidity and mortality trial.

In the dronedarone arm of the studies, no episodes of ‘’torsades de pointes,’’ a serious ventricular arrhythmia observed with some existing treatments, were reported at one year and the incidence of adverse events (pulmonary toxicity, thyroid and liver dysfunction) was not significantly increased. In both studies, hyperthyroidism occurred less frequently in the dronedarone group versus placebo (8.4% vs 14.1%, P=0.0024) and elevated serum creatinine concentrations, which in some cases were reversible, occurred more frequently in the dronedarone group versus placebo (2.4% vs 0.2%, P=0.0039) without impact on renal function. Most common adverse events occurring in more than two percent of dronedarone treated patients, not statistically different from placebo, included cough, dyspnoea, hypothyroidism, bradycardia/conduction block, heart failure/shock, diarrhea, nausea, and liver function abnormalities.

"Our findings demonstrating no increased risk of pulmonary toxicity, thyroid or liver dysfunction are important because there are few treatment options for patients with AF and AFL that are not associated with serious side effects," Dr Singh said. "The low incidence of adverse events in the study was encouraging. It is also important to note that there were no cases of torsades de pointes.”

About Atrial Fibrillation/Flutter

AF is the most common arrhythmia requiring hospitalization and is associated with increased morbidity and mortality. AF can cause palpitations, shortness of breath and fatigue.

AFL is an abnormal fast heart rhythm that occurs in the atria of the heart. This rhythm occurs most often in individuals with other heart conditions (e.g., pericarditis, coronary artery disease, and cardiomyopathy). AFL frequently degenerates to atrial fibrillation. However, it may persist for months to years.

Restoring sinus rhythm in AF is often associated with improvement in exercise capacity and quality of life, making sinus rhythm restoration and maintenance one of the therapeutic goals in AF.

About EURIDIS/ADONIS

EURIDIS and ADONIS were two identical placebo-controlled, multi-center, double-blind, parallel-group trials. EURIDIS was conducted in 12 European countries and ADONIS was conducted in the United States, Canada, Australia, South Africa, and Argentina. The studies were conducted in an out-patient population. 612 patients were randomized in EURIDIS and 625 in ADONIS. A total of 1,237 patients have been included in the two studies.

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Enrollment criteria were at least one arrhythmic episode during the previous three months and sinus rhythm for at least one hour before randomization to dronedarone 400 mg twice-daily or placebo. Rhythm was monitored on days 2, 3, 5; at 3, 5, 7, and 10 months; during symptomatic arrhythmia recurrence; and during 9 scheduled visits over 12 months. Regular ECG's were also transmitted when patients were asymptomatic. The primary end point was time from randomization to first documented AF/AFL recurrence.

About Dronedarone (MULTAQ™)

Dronedarone is a novel multi-channel blocker, anti-arrhythmic drug (AAD) under development, discovered and developed by sanofi-aventis for the treatment of atrial fibrillation and atrial flutter.

About sanofi-aventis

Sanofi-aventis is one of the world leaders in the pharmaceutical industry, ranking number one in Europe. Backed by a world-class R&D organization, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines. 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 financial 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 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, 2006. Other than as required by applicable law, sanofi-aventis does not undertake [i] any obligation to update or revise any forward-looking information or statements.

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