News Releases

Sanofi-aventis Initiates 10,000 Patient Study With Multaq® in Permanent Atrial Fibrillation

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- New Outcomes Trial to Expand Evidence for Dronedarone in a Different AF Population

PARIS, May 12 /CNW/ - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today the initiation of a multinational, randomized, double-blind Phase IIIb trial, PALLAS, to assess the potential clinical benefit of Multaq® (dronedarone) in over 10,000 patients with permanent atrial fibrillation (AF) to reduce major adverse cardiovascular events. The announcement was made during Heart Rhythm 2010, the Heart Rhythm Society's 31st Annual Scientific Sessions.

To view the Multimedia News Release, please click:

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Permanent AF afflicts 50% of patients suffering from AF and these patients are at high risk of major adverse cardiovascular events. The trial rationale was based on post-hoc findings from the landmark ATHENA trial, in which a trend towards reduction of CV hospitalization and death was seen in patients classified as "permanent" (i.e. with AF/AFL at each ECG recording).

"This is a trial of major significance since no anti-arrhythmic drug has ever been shown to reduce major morbidity and mortality in permanent AF patients in a large-scale clinical trial," said Stuart Connolly, MD, Division of Cardiology, McMaster University, Hamilton, Canada, one of the trial's principal investigators. "We designed the PALLAS trial to further assess the role of Multaq® to reduce cardiovascular outcomes in patients with AF."

The primary objective of the PALLAS trial is to demonstrate a reduction in either or both of two composite outcomes which are 1. major cardiovascular events (stroke, systemic arterial embolism, myocardial infarction or cardiovascular death) or 2. cardiovascular hospitalization or death from any cause among patients with permanent atrial fibrillation and additional risk factors. The secondary objectives are to evaluate the efficacy of Multaq® in preventing cardiovascular death and whether the drug is well-tolerated in this patient population.

"The initiation of the PALLAS trial confirms our strong belief in Multaq® and our commitment to improve AF patient well-being and overall cardiovascular health," said Marc Cluzel, MD, Executive Vice President, Research and Development, sanofi-aventis. "We are looking forward to first patient enrolment of PALLAS in the third-quarter 2010."

About PALLAS

PALLAS* is a multinational, randomized, double-blind, parallel-group, placebo-controlled, multicenter Phase IIIb trial comparing the efficacy of Multaq® 400mg twice-daily with placebo in permanent AF patients. All patients will receive standard treatment to control heart rate and prevent blood clots (antithrombotic therapy); patients will be randomized to receive additional treatment with either Multaq® 400mg BID or placebo.

Required risk factors include age above 65 years with at least one of the following major risk factors: systemic arterial embolism, myocardial infarction, documented coronary artery disease, prior stroke, symptomatic heart failure, or the combination of age above 75 years, hypertension and diabetes mellitus. Exclusion criteria include patients with New York Heart Association (NYHA) Class IV heart failure or unstable NYHA Class III heart failure.

The trial has two composite co-primary endpoints: 1. Major cardiovascular events (stroke, systemic arterial embolism, myocardial infarction or cardiovascular death). 2. Cardiovascular hospitalization or death from any cause.

There will be 10,800 patients enrolled in 43 countries at 700 sites. The trial is event-driven with a fixed Common Study End Date, meaning that the study duration will depend upon the occurrence of a statistically required number of outcome events.

* Permanent Atrial fibriLLAtion outcome Study using Dronedarone on top of standard therapy (PALLAS)

About Permanent Atrial Fibrillation

The incidence of atrial fibrillation is growing worldwide in relation to aging populations. It is emerging as a

public health concern, affects about 4.5 million people in Europe and represents one-third of hospitalizations for arrhythmia in the European Union. Atrial fibrillation leads to potential life-threatening complications. AF increases the risk of stroke up to five-fold, worsens the prognosis of patients with cardiovascular risk factors, and doubles the risk of mortality with significant burden on patients, health care providers and payers. Seventy percent of AF management costs are driven by hospital care and interventional procedures in the European Union.

According to ACC/AHA/ESC guidelines, permanent AF is the designation given when sinus rhythm cannot be sustained after cardioversion of AF (medical intervention designed to restore sinus rhythm) or when the patient and physician have decided to allow AF to continue without further efforts to restore sinus rhythm(i). In the Euro Heart Survey one year follow-up, one year mortality in patients suffering from AF was high and the risk continuously present. Mortality (5.3%) was comparable with results of previous studies, which is also the case for the observed higher mortality in permanent AF than in other AF types(ii).

About Multaq®

Multaq®, discovered and developed by sanofi-aventis, has been studied in a clinical development program, including seven international, multicenter, randomized clinical trials involving more than 7000 patients with almost 4000 patients receiving Multaq®. The landmark ATHENA trial was the largest anti-arrhythmic drug trial conducted in patients with AF/AFL, involving 4,628 patients with a follow-up of 30 months. In this trial, Multaq®, on top of standard cardiovascular therapy, significantly reduced cardiovascular hospitalization or death by 24 percent (p less than 0.001) when compared to placebo, meeting the study's primary endpoint. This result was entirely attributable to a reduction in cardiovascular hospitalization.

Multaq® has a fixed dose regimen of twice daily 400 mg tablets to be taken with morning and evening meals. Treatment with Multaq® does not require a loading dose and can be initiated in an outpatient setting. Most common adverse reactions are diarrhea, nausea, vomiting, abdominal pain, asthenia (weakness) and skin rash.

The European Commission granted marketing authorization for Multaq® in November 2009. Multaq® is indicated in the EU in adult clinically stable patients with a history of, or current non-permanent atrial fibrillation (AF) to prevent recurrence of AF or to lower ventricular rate. The use of Multaq® in unstable patients with NYHA class III and IV heart failure is contraindicated. Because of limited experience in stable patients with recent (1 to 3 months) NYHA class III heart failure or with Left Ventricular Ejection Fraction (LVEF) less than 35%, the use of Multaq® is not recommended in these patients(iii).

In the U.S., Multaq® is 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 greater than 70, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter greater-than-or-equal-to 50 mm or left ventricular ejection fraction (LVEF) less than 40%), who are in sinus rhythm or who will be cardioverted(iv). 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.

Multaq® is currently available in the U.S., Canada, Switzerland, Germany, Denmark, Ireland, Norway, Finland and the UK and is being launched in most European countries in 2010.

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). For more information, please visit: http://www.sanofi-aventis.com.

Forward-Looking Statement

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 projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential 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 EMA, 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 product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities 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, 2009. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

(i) Fuster V, Ryden LE, Cannom DS, et al. ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. Circulation 2006;114(7):e257-354.

(ii) Nieuwlaat R, Prins MH, Le Heuzey JY, et al. Prognosis, disease progression, and treatment of atrial fibrillation patients during 1 year: follow-up of the Euro Heart Survey on atrial fibrillation. Eur Heart J 2008;29(9):1181-9.

(iii) European Medicines Agency. European Public Assessment Report. Doc. Ref.: EMA/625172/2009; EMEA/H/C/1043

(iv) MULTAQ U.S. Prescribing information http://products.sanofi-aventis.us/Multaq/Multaq.pdf

Video: http://multivu.prnewswire.com/mnr/prne/sanofiaventis/42428/

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