Sanofi Provides Multaq® Phase IIIb PALLAS Trial Update

- Indication seeking trial in permanent AF patient population stopped -

- Benefit-risk of Multaq remains unchanged in non-permanent AF patients -

Paris, France – July 7, 2011 - Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that the company has discontinued the PALLAS Phase IIIb trial in patients with permanent Atrial Fibrillation (AF), a population different from the population with non-permanent AF for which Multaq® (dronedarone) is currently approved. The decision follows recommendations from the study's Operations Committee and the Data Monitoring Committee (DMC) which observed a significant increase in cardiovascular events in the dronedarone arm. The decision to terminate the study was not related to any hepatic adverse event.

Sanofi has informed regulatory authorities of this decision. The company also has asked all PALLAS clinical investigators to inform their patients included in the trial to stop taking the study medication and consult their clinical trial center. This direction applies to the PALLAS study patients only.

The benefit-risk of Multaq remains unchanged in its approved indication in non-permanent AF. Patients currently taking Multaq should not stop their therapy and should consult their treating physician should they have any questions.

"Patient safety is of highest priority for Sanofi. We are notifying regulatory authorities in all countries where the product is approved or under review on this matter," said Jean-Pierre Lehner, MD, Chief Medical Officer, Sanofi. "*We remain committed to Multaq as an essential treatment option for non-permanent AF patients."*

Atrial fibrillation is a serious disease associated with an increase in premature mortality. There are two types of AF patients, non-permanent and permanent (with AF for at least 6 months). Permanent AF patients are at an even higher increased risk of major adverse cardiovascular events as compared to non-permanent AF patients, the populations in which Multaq is currently approved.

"Patients with permanent AF and vascular risk factors are at high risk of major vascular events and no previous study has investigated whether any intervention can reduce major morbidity or mortality in these patients. PALLAS is the first trial to investigate whether an anti-arrhythmic drug can decrease outcomes in this important population of patients," said Stuart Connolly, M.D., Division of Cardiology, McMaster University, Hamilton, Canada, and the PALLAS trial's co- principal investigator. *"The PALLAS Operations Committee is very disappointed to discover that the hypothesis that dronedarone would improve major outcomes for this high risk patient population has been refuted."*

The patient population included in the PALLAS study is different from the population for which Multaq is currently approved. In the PALLAS population, 70% of the 3,149 patients enrolled had permanent AF for over 2 years; approximately 70% had NYHA heart failure Class I to III at baseline.

In contrast, in the study supporting the current indication (ATHENA), no patients enrolled had permanent AF and less than 30% of patients had NYHA heart failure Class I to III. PALLAS patients were also older than ATHENA patients.

Multaq is currently approved 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. 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 >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.

Currently approximately 400,000 patients have been treated with Multaq worldwide.

About PALLAS

PALLAS (Permanent Atrial fibriLLAtion outcome Study using Dronedarone on top of standard therapy) was a multinational, randomized, double-blind, parallel-group, placebo-controlled, multicenter Phase IIIb trial comparing the efficacy of dronedarone 400mg twice-daily to placebo in permanent AF patients. Patients were required to have an age above 65 years with co-morbid conditions, such as 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 included New York Heart Association (NYHA) Class IV heart failure or unstable NYHA Class III heart failure.

The trial had 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.

About Permanent Atrial Fibrillation

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. 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.

About Multaq®

Multaq®, discovered and developed by Sanofi, 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 non-permanent 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 ($p<0.001$) 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) <35%, the use of Multaq® is not recommended in these patients.

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 >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.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 32 countries and is recommended as a first line treatment option in the majority of AF patients by the ESC and ACC/AHA Guidelines. 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 Multaq had a greater than two-fold increase in mortality. Such patients should not be given Multaq.

About Sanofi

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, rare diseases, consumer healthcare, emerging markets and animal health. Sanofi 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 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's 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, 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 labeling 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, 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, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2010. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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