Sanofi-aventis Launches Major New Registry Including Over 10,000 patients Worldwide with Atrial Fibrillation

- The RealiseAF registry will help to better define and understand the cardiovascular risk profile of AF patients and characterize their cardiovascular outcomes -

Paris, France, November 16, 2009 - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today the launch of the RealiseAF registry (**Rea**l **Li**fe global **S**urvey **E**valuating patients with **A**trial **F**ibrillation), an international, cross-sectional, observational registry that will be conducted in patients with atrial fibrillation (AF). This disease can worsen patients' prognosis, increase the risk of hospitalization, stroke and mortality. RealiseAF will provide a real-life picture of the global burden of AF in more than 10,000 patients in 27 countries.

"Sanofi-aventis is a major contributor to the efforts to reduce the public health burden of atrial fibrillation" said Jean-Pierre Lehner, Chief Medical Officer, sanofi-aventis*. "The company strives to respond to the medical needs of patients and physicians, not only with innovative therapeutic solutions, but also via investment in registries such as RealiseAF, dedicated to furthering the understanding of the risk profiles of patients with atrial fibrillation."*

RealiseAF is designed to assess the control of atrial fibrillation (AF) and investigate the CV risk profile of a broad spectrum of AF populations in Europe, Latin America, Asia, Middle East and North Africa. This new registry is intended to generate new data on a broad AF population including patients with paroxysmal, persistent as well as permanent atrial fibrillation, AF due to transient causes. It will provide a better understanding of this disease and associated CV consequences, which may help to further improve the burden of AF.

"RealiseAF will provide more data to help physicians to understand the true impact of AF, its burden and how to improve outcomes," said Professor G. Steg, Department of Cardiology, Hôpital Bichat, Paris, France, on behalf of the RealiseAF steering committee*. "This study will give us a unique picture both globally and locally about the AF patient population and how patients are managed."*

RealiseAF was designed to complement the results of the RecordAF registry (Registry on Cardiac Rhythm Disorders, an international, observational, prospective survey assessing the control of Atrial Fibrillation), presented during the late breaking session of the American Heart Association 2009 meeting in Orlando, USA. The results of the RecordAF registry show that 18% of all patients had cardiovascular (CV) clinical events at 1 year mainly driven by CV hospitalization. A rhythm control strategy was preferred by 55% of cardiologists and achieved better therapeutic success than a rate control strategy (60% vs 47%). Nevertheless, rhythm control strategies with existing therapies at the time of this study did not translate into better outcomes than rate control.

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None of these 2 strategies appeared to be really satisfactory for physicians; 22% of physicians changed their strategy and 52% modified AF treatment within a strategy during the 12 months period. These results highlight the need for newer anti-arrhythmic drugs able to successfully achieve rhythm and rate control as well as decrease clinical events.

The recruitment of the RealiseAF patients recently started at the end of October 2009 and final results are expected by the end of 2010. RealiseAF is supported by an unrestricted educational grant from sanofi-aventis.

About RealiseAF

The RealiseAF registry will follow more than 10,000 patients in 926 centers from 27 countries with a history of atrial fibrillation and at least one AF episode in the last 12 months, or documented current AF.

Adults with paroxysmal, persistent as well as permanent AF, and AF due to transient causes (thyrotoxicosis, alcohol intoxication, acute phase of myocardial infarction, pericarditis, myocarditis, electrocution, pulmonary embolism or other pulmonary disease, hydroelectrolytic disorder, metabolic disorder, etc.) are included.

Data collected will include the following measures: family and personal cardiovascular risk factors, history of comorbidities, cardiovascular events leading to hospitalisation in the last 12 months, cardiovascular interventions, history and characteristics of AF, AF management, and quality of life assessment. Cardiologists (office-based and hospital-based) and internists will be randomly selected to participate in the study.

About RecordAF

The RecordAF registry recruited 5,604 patients with recent onset atrial fibrillation from 21 countries spanning North and South America, Europe and Asia. They were studied for a period of one year. The primary outcomes of the study were therapeutic success and clinical outcomes associated with rhythm- and rate-control strategies. Therapeutic success at 1 year required that treatment strategy was unchanged, that no clinical events occurred during follow-up, and that sinus rhythm was achieved in the rhythm-control group or the heart rate ≤80 bpm in the rate-control group.

Physicians involved in the registry were randomly selected from an initial representative and exhaustive global list of office- and hospital-based cardiologists.

About atrial fibrillation

Atrial fibrillation is the most common cardiac arrhythmia and affects nearly 7 million people in the European Union and the United States[1]. AF currently represents a major economic burden for society and leads to potential life-threatening complications. AF increases the risk of stroke up to five-fold[2], worsens the prognosis of patients with cardiovascular risk factors[3], and doubles the risk of mortality[4] with significant burden on patients, health care providers and payers. Hospitalizations for AF have increased dramatically (two-to-three-fold) in recent years[1]. AF hospitalizations now represent a third of all hospitalizations for arrhythmia and mortality in the US and Europe[3]. Seventy percent of the annual cost of AF management in Europe is driven by hospital care and interventional procedures[5].

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, visit: www.sanofi-aventis.com

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