

Largest Atrial Fibrillation Registry Reveals Poor AF Control and High Rates of Cardiovascular Hospitalization

- Over 10,000 Patients Included in RealiseAF -

Paris, France – September 1, 2010 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that results from the *RealiseAF* (Real-life global survey evaluating patients with Atrial Fibrillation) registry show that control of atrial fibrillation (AF) (defined by the 2006 ACC/AHA/ESC AF guidelines as either sinus rhythm or AF with heart rate at rest \leq 80 bpm)¹ was not achieved in more than 40 percent of the AF patients included in this 10,000 patient cross-sectional registry, as presented today during the European Society of Cardiology Congress in Stockholm, Sweden. In addition, the registry revealed that a majority of patients complain of symptoms, even when AF is controlled² (55.7 percent).

Importantly, cardiovascular (CV) events were very frequent in this population, with a high rate of concomitant CV risk factors (72.2% of patients were hypertensive and 46.3% of patients had dyslipidemia) 28.7 percent of AF patients suffered from CV events such as acute coronary syndrome (ACS) acute heart failure or stroke, leading to an unplanned hospitalisation during the last 12 months and 12.4 percent of patients requiring major CV interventions such as Percutaneous Coronary Intervention (PCI), Coronary Artery Bypass Graft (CABG) or valvular surgery.

Management of AF in a real-life setting shows that today, AF is not treated according to the 2006 ACC/AHA/ESC AF guidelines:

- 20 percent of AF patients with structural heart disease received Class Ic AADs, despite its contraindication in this patient population.
- 49.9 percent of evaluated paroxysmal and persistent AF patients without congestive heart failure (CHF) or hypertension with significant left ventricular hypertrophy received amiodarone as a first-line treatment, despite guidelines recommendations that it be used as a second line agent.
- In addition, patients with a CHADS2 \geq 2 who should receive anti-coagulants agents only received these agents in 52 percent of cases.

“The RealiseAF registry shows that patients suffering from atrial fibrillation not only require symptom relief but management which goes beyond heart rate or rhythm control, and addresses event-driven hospitalisations,” said Professor Ph. Gabriel Steg, Department of Cardiology, Hôpital Bichat, Paris, France, on behalf of the *RealiseAF* steering committee. *“The data suggest a need for new therapies and an increased focus on cardiovascular outcomes, as well as a more stringent adherence to guidelines.”*

About RealiseAF

RealiseAF is a large international cross-sectional registry established in 2009 to determine the rate of AF control and establish the burden of cardiovascular (CV) disease in typical patients with AF.

RealiseAF is coordinated by an independent scientific committee of international experts in cardiology and electrophysiology, and uses a comprehensive data collection strategy. Building on the success of previous registries, including RecordAF and the European Heart Survey on AF, *RealiseAF* provides a reliable assessment of the CV risk profile of patients with AF, the types of treatment they receive, and how these factors influence outcomes in a real-world setting.

The registry was launched in November 2009 and the database locked in June 2010. More than 10,000 patients from 26 countries were enrolled. Participating countries included: Algeria, Azerbaijan, Belgium, Bulgaria, Czech Republic, Egypt, Germany, Hungary, India, Ireland, Italy, Lebanon, Lithuania, Mexico, Morocco, Portugal, Russia, Slovakia, Spain, Sweden, Switzerland, Taiwan, Tunisia, Turkey, Ukraine and Venezuela.

The registry *RealiseAF* was sponsored by sanofi-aventis.

About atrial fibrillation

Atrial fibrillation affects close to 7 million people in the USA and the EU alone. By 2050, the prevalence of AF in the USA is predicted to more than double. As a growing international health concern, AF is associated with an increase in morbidity and mortality, particularly due to cardiovascular (CV) events leading to an increased risk of hospitalisation, which contributes considerably to healthcare costs.

For more information, please visit: <https://www.realiseaf.org>.

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).

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1. Fuster V et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation. *European Heart Journal* (2006) 27, 1979-2030.
2. Steg, P. "The REALISE-AF registry: an international, observational, cross-sectional survey describing characteristics, cardiovascular risk, and management of patients with atrial fibrillation." Presented at the European Society of Cardiology Congress, Sept. 1, 2010. Program number 5080. <http://spo.escardio.org/SessionDetails.aspx?id=331012>