

Sanofi-aventis: Multaq® Approved in the European Union for Patients With Atrial Fibrillation

- First New Anti-Arrhythmic Drug to be Approved in the European Union in the Last 10 Years

PARIS, Nov. 30 /CNW/ - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that the European Commission has granted marketing authorization for Multaq® (dronedarone - 400mg Tablets) in all 27 European member states. This approval follows the European Commission positive opinion issued on September 25, 2009 by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine agency (EMA).

Multaq® is indicated 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.

Multaq® discovered and developed by sanofi-aventis is the first anti-arrhythmic drug approved in the European Union that has shown a clinical benefit to reduce cardiovascular hospitalizations or death from any cause in patients with AF/AFL as described in the ATHENA trial.

"The approval of Multaq® in the European Union is important news for atrial fibrillation patients who will now have access to a new treatment approach," said Marc Cluzel, MD, Executive Vice President, Research and Development, sanofi-aventis. "The approval of Multaq® is the result of more than 15 years of research and development conducted by sanofi-aventis and supported by the commitment of the experts involved in the clinical development program and AF patients participating in the trials."

The use of dronedarone 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.

The marketing authorisation of Multaq® was based on the review of a comprehensive clinical data package including seven international, multi-center, randomized clinical trials involving more than 7000 patients with almost 4000 patients receiving dronedarone during the clinical development program.

"This European approval is good news for doctors and patients since atrial fibrillation affects about 4.5 million people in Europe and represents one-third of hospitalizations for arrhythmia in the European Union" said Dr. Stefan H. Hohnloser J.W., Goethe University's Division of Clinical Electrophysiology, Frankfurt, Germany, principal investigator of the ATHENA study. "Multaq® is a significant step forward which could change the way we approach the management of atrial fibrillation and offers a new treatment option to physicians in a field where there has been no significant anti-arrhythmic drug innovation for almost 20 years."

The first launches of Multaq® are expected to take place in the United Kingdom and Germany in January 2010. Multaq® is already approved in the United States, Canada, Switzerland and Brazil.

About dronedarone (Multaq®)

The marketing authorisation of Multaq® was based on the review of four placebo controlled studies in patients with atrial fibrillation (AF) or atrial flutter (AFL) called EURIDIS, ADONIS, ERATO and ATHENA; the DIONYSOS trial, a comparative trial vs amiodarone; and the ANDROMEDA trial, a placebo controlled study in heart failure patients with a recent hospitalization for decompensated systolic heart failure.

The landmark ATHENA trial was the largest anti-arrhythmic drug trial ever conducted in patients with AF/AFL, involving 4,628 patients with a follow-up of 30 months. In this trial, dronedarone, on top of standard therapy, significantly reduced cardiovascular hospitalization or death by 24 percent when compared to placebo, meeting the study's primary endpoint. This reduction was generally consistent across study subgroups based on baseline characteristics or medications.

The most common adverse reactions were diarrhea, nausea, vomiting, abdominal pain, asthenia (weakness) and skin rash.

Dronedarone has a convenient fixed dose regimen of twice daily 400 mg tablets to be taken with morning and evening meals. Treatment with dronedarone does not require a loading dose and can be initiated in an outpatient setting with minimal monitoring

The EURIDIS-ADONIS, ANDROMEDA and ATHENA trials were published in the New England Journal of Medicine (NEJM) respectively in 2007, 2008 and 2009.

About 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(1). Atrial fibrillation 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. Seventy percent of AF management costs are driven by hospital care and interventional procedure in the European Union(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).

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 product development, product potential 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 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 EMEA, 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 products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives 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, 2008. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

References:

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- (2) Lloyd-Jones et al. Lifetime Risk for Development of Atrial Fibrillation: The Framingham Heart Study. Circulation. 2004; 110:1042-1046.
- (3) Fuster V et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation. European Heart Journal (2006) 27, 1979-2030.
- (4) Benjamin EJ, Wolf PA, D'Agostino RB, Silbershatz H, Kannel WB, Levy D. Impact of atrial fibrillation on the risk of death: the Framingham Heart Study. Circulation 1998 Sep 8; 98(10):946-52..
- (5) Ringborg et al, Europace 2008 10; 400-411

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