News Releases

Sanofi-aventis: Multaq® Receives Positive Recommendation by NICE in New Appraisal Consultation Document

PARIS, March 30 /CNW/ - Sanofi-aventis (EURONEXT: SAN, and NYSE: SNY) announced today that the National Institute for Health and Clinical Excellence (NICE) in England and Wales, has just published a new appraisal consultation document (ACD)(1) for Multaq® (dronedarone) indicating its intention to recommend Multaq® use for the management of patients with atrial fibrillation (AF).

The NICE appraisal committee's preliminary recommendation is to endorse Multaq® as a first choice therapeutic option after beta-blockers, which are the initial therapeutic option in the NICE clinical guidelines. Based on this recommendation, Multaq® should be prescribed in non-permanent AF patients with at least one of the following cardiovascular risk factors: hypertension requiring drugs of at least two different classes, diabetes mellitus, previous transient ischemic attack, stroke or systemic embolism, left atrial diameter of 50mm of greater, LVEF less than 40% or age 70 years or older and who do not have unstable New York Heart Association (NYHA) class III or IV heart failure.

This patient population corresponds to the patients included in the landmark ATHENA study, the largest study ever performed with an anti-arrhythmic drug in atrial fibrillation and the only study to have ever demonstrated a positive impact on cardiovascular (CV) morbidity and mortality.

In ATHENA, Multaq® reduced the risk of cardiovascular hospitalization or death by a significant 24% vs. placebo on top of standard of care including beta-blockers (p(less than)0.001) with no difference in the rate of serious adverse events (19.9% vs 21.1% respectively; p = 0.31).

"Sanofi-aventis is pleased that NICE has acknowledged the benefits of Multaq® for non-permanent AF patients who have been awaiting a new therapeutic option that safely treats their symptoms and improves their long-term cardiovascular outcomes," declared Belen Garijo, Senior Vice President, Pharmaceutical Operations Europe, sanofi-aventis. "We appreciate the thorough and comprehensive evaluation of the Multaq® clinical and economic dossier that NICE has performed and believe that this preliminary recommendation by NICE provides a valuable benchmark to guide sanofi-aventis' ongoing efforts to have the Multaq® value proposition in AF patients recognized within Europe and beyond."

Multaq® will be commercially available in the UK from today, Tuesday, March 30, 2010.

About Multaq®

Multaq®, discovered and developed by sanofi-aventis, has been studied in a clinical development program, including seven international, multi-center, 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.(2) 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.

Multaq® is currently available in the U.S., Canada, Switzerland, Germany, Denmark, Ireland, Norway and Finland 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).

About NICE

The National Institute for Health and Clinical Excellence (NICE) is the independent organization in the United Kingdom responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. NICE produces guidance on the use of new and existing medicines, treatments and procedures within the UK National Health Service (NHS). NICE technology appraisal recommendations are prepared by independent advisory committees called Technology Appraisal Committees, which issue an Appraisal Consultation Document (ACD). The NHS is legally obliged to fund (reimburse) and resource medicines and treatments recommended by NICE's technology appraisals.

About the NICE process for Multaq®

- The stakeholder consultation period for this ACD closes on 22 April
  - Stakeholder comments submitted to NICE on this ACD will be considered at the Appraisal Committee Meeting on 26 May
  - If a Final Appraisal Determination (FAD) is produced following the Appraisal Committee Meeting it would be expected in early July
  - If the FAD is not appealed, publication of Final Guidance would be expected sometime between July and September.

1. This new appraisal document is not the final NICE guidance on Multaq®. A consultation period is ongoing until April 22nd, 2010. The appraisal committee will meet again to consider the evidence on May 26, 2010.

After this meeting the Committee will prepare the final appraisal determination (FAD) for Multaq®.

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 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-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.

References:

(1) Hohnloser S.H, Crijns H.J.G.M., van Eickels M, et al. Effect of Dronedarone on Cardiovascular Events in Atrial Fibrillation, N Engl J Med 2009; 360:668-78.

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

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