



European Medicines Agency (EMA) confirms positive benefit-risk balance for Multaq[®]

- European Prescribing Information Updated to Ensure Multaq[®] Use in Appropriate Paroxysmal and Persistent AF Patients -

Paris, France - September 22, 2011 - Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) confirmed a positive benefit-risk balance for Multaq[®] (dronedarone) for the treatment of a newly defined population of paroxysmal and persistent Atrial Fibrillation (AF) patients, following its review under the Article 20 procedure.

The EMA has defined Multaq[®]'s role in the treatment of paroxysmal and persistent AF stating that the Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Multaq[®] continue to outweigh the risks for a limited population of patients with Atrial Fibrillation.

The new indication for Multaq is: "Multaq[®] is indicated for the maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation (AF). Due to its safety profile (see sections 4.3 and 4.4) Multaq[®] should only be prescribed after alternative treatment options have been considered. Multaq[®] should not be given to patients with left ventricular systolic dysfunction or to patients with current or previous episodes of heart failure."

A Direct Healthcare Professional Communication (DHPC) letter informing healthcare providers of the updates to the Multaq[®] SPC (Summary of Product Characteristics) will be issued in the European Union member states where Multaq[®] (dronedarone) is currently available.

"The CHMP opinion is significant as it ensures availability of an important treatment option for paroxysmal and persistent atrial fibrillation, a growing public health concern associated with life threatening consequences," said Dr. Jean-Pierre Lehner, Chief Medical Officer, Sanofi.

Multaq[®] is launched in 37 countries worldwide and has been prescribed to over 440,000 patients to date.

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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