Sanofi-aventis press release

Sanofi-aventis Receives Complete Response Letter from the FDA for Eplivanserin (Ciltyri®) Submission

Paris, France – September 16, 2009 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that the U.S. Food and Drug Administration (FDA) has issued a complete response letter regarding the company's New Drug Application (NDA) for eplivanserin (Ciltyri[®]). Eplivanserin was reviewed as a potential treatment for patients with chronic insomnia characterized by difficulties with sleep maintenance.

Sanofi-aventis is currently reviewing the content of the complete response letter, in which the FDA has requested additional information regarding benefit-risk. The company will contact the FDA in the coming days to request a meeting to discuss what steps and data would be needed for approval.

About eplivanserin (Ciltyri®)

Eplivanserin, discovered and developed by sanofi-aventis, is a serotonin type 2 A receptor antagonist, and unlike benzodiazepine-receptor agonists (BzRAs), has no affinity for GABA receptors. It has been studied in a clinical development program including nearly 3,000 patients.

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 quarantee 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.

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