

Sanofi-aventis expresses concern over the approval of another version of enoxaparin sodium in the U.S.

Paris, France – July 23, 2010 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) has reservations on today's approval by the U.S. Food and Drug Administration (FDA) of another version of enoxaparin sodium. As a responsible healthcare company, sanofi-aventis is concerned by potential implications for patient safety, since the product approved today has not been subjected to extensive clinical trials to demonstrate its efficacy and safety as sanofi-aventis has done with its product Lovenox® (enoxaparin sodium). By nature, Lovenox® is a complex biological product and its efficacy and safety profile relies heavily on the strict adherence to the specific processes applied in its manufacturing as well as its traceability from the animal mucosa to the finished product.

“Prevention and treatment of thrombo-embolism is a major public health issue,” said Professor Job Harenberg, MD, Professor of Medicine at the Faculty of Clinical Medicine Mannheim, University of Heidelberg. *“There are significant challenges to demonstrating therapeutic equivalence of a complex biological product such as enoxaparin without direct comparative clinical trials to assess efficacy, and even more importantly safety as published in the Consensus recommendation on biosimilars LMWHs¹. Physicians and patients need to remain fully confident that when they use enoxaparin they will have consistent access to the highest quality products to treat such life-threatening conditions.”*

As a worldwide leader in the field of low-molecular weight heparins, sanofi-aventis has been regularly communicating with the FDA since the 1980's on the quality standards of enoxaparin sodium and most recently through a Citizen's Petition to share the company knowledge on heparins. However, the FDA-approved version has not been assessed on the basis of an extensive clinical program showing proven and comparable clinical efficacy and safety to Lovenox®. Lovenox® is the most widely studied LMWH in the world, with more than 16 years of clinical and real-world experience in the U.S.

Sanofi-aventis will avail itself of appropriate analytical and clinical avenues to assess the quality, efficacy and safety of the product and is considering all appropriate legal options.

Sanofi-aventis is committed to making healthcare professionals aware of the complexities related to the biologic composition and manufacturing of Low Molecular Weight Heparins and Lovenox®, so that they can make informed decisions about the best treatment option for their patients.

Lovenox® is a global product. Introduction of another version of enoxaparin sodium in the US would compete with less than 60% of overall Lovenox®/Clexane® sales. Lovenox® sales outside of the US have been growing faster than in the US and represent more than 40% of Lovenox total sales in 2009. Regulations for biosimilars requiring comparative studies for low molecular weight heparins exist in Europe and Australia.

As a preliminary guidance, the Group expects business EPS for the year 2010 to be stable to down 4% versus 2009, at constant exchange rates. The group reiterates its 2013 objectives as announced in July 2009.

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 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.

1. *Recommendations on biosimilar low-molecular weight heparins, J.Harenberg et al. on behalf of the Subcommittee on control of Anticoagulation of the SSC of the ISTH
Journal of Thrombosis and Haemostasis,2009; 7: 1222-1225*