# Sanofi-aventis is complying with the EMEA's recommendation to temporarily suspend the marketing authorisation of Acomplia® in obese and overweight patients

- Sanofi-aventis will comply with the European Authorities request to temporarily suspend the marketing authorisation of Acomplia® in obese and overweight patients and will make every effort to actively support patients and Health Care Professionals in this process.
- Sanofi-aventis is committed to provide additional evidence for the re-evaluation of the benefit / risk profile of Acomplia® in patients with diabetes and cardiovascular diseases through the ongoing clinical studies.
- Sanofi-aventis remains committed to Acomplia® to bring an important therapeutic approach to obese and overweight patients.

**Paris, October, 23, 2008 -** Sanofi-aventis announced today that the European Medicines Agency (EMEA) has recommended to the European Commission (EC) the temporary suspension of the marketing authorisation of Acomplia® (rimonabant) for the approved indication of overweight and obese patients.

Acomplia® has been marketed in 18 EU countries since 2006 and has provided significant clinical benefits to patients suffering from obesity and overweight with associated co-morbidities.

Since the start of the commercialisation of Acomplia®, sanofi-aventis has been closely collaborating with both the regulatory authorities and healthcare providers to monitor on an ongoing basis the real life use of the product and to ensure its use in the right patient population.

More than 700,000 patients have been treated with Acomplia® world-wide to date. In the postmarketing surveillance of Acomplia the safety profile of the product is aligned to the one described in the current European SmPC for the product and is consistent with the one observed during the clinical development.



"This first in its class medication continues to demonstrate great promise to reduce cardiometabolic risk and the pattern of side effects remains consistent across the randomized clinical trials conducted to date. As with any new drug category, more will be learned about optimizing benefit and minimizing risk through continuing controlled use of the medication in different patient populations. While the pendulum has swung in the direction of extreme caution with today's regulatory decision, at the end of the day, the medical community will allow the scientific process to unfold before rendering any final decisions about this medication's ultimate therapeutic potential" declared Robert Anthenelli, M.D. Professor of Psychiatry, Psychology and Neuroscience University of Cincinnati College of Medicine and Cincinnati Veterans Affairs Medical Center.

Sanofi-aventis believes that Acomplia® will remain an important therapeutic answer to a highly prevalent and increasing unmet medical need. As discussed with the EMEA, sanofi-aventis will continue the ongoing clinical trial program except phase IV and is committed to provide additional evidence for the positive re-evaluation of the benefit / risk profile of Acomplia®, including through studies in diabetes and in patients at risk of cardiovascular disease.

Inline with its commitment to the EMEA, sanofi-aventis and its subsidiaries will inform Health Care Professionals as of today of the temporary marketing authorisation suspension. Patients who are currently taking Acomplia® should consult their doctor or pharmacist at a convenient time to discuss their treatment.

Sanofi-aventis will enter immediately in discussion with health care authorities in non European Union countries where Acomplia is available to determine how to implement an equivalent EMEA decision.

\* \* \*

A conference call on Acomplia will be organized by the company, today: October 23, 2008 at 6:00 p.m. Paris time. It will be hosted by:

Dr. Marc Cluzel – Senior Vice President – R&D
Dr. Jean-Pierre Lehner – Senior Vice President – Medical and Regulatory Affairs
Jean-Claude Leroy – Executive Vice-Président – Finance and Legal

This conference will be followed by a Q&A session.

The conference will be available by telephone via the following numbers.

It will also be available in a hear-only mode on our website: <a href="http://www.sanofi-aventis.com">http://www.sanofi-aventis.com</a>

**CALL-IN NUMBERS** The conference will be available by telephone via the following numbers:

France +33 (0)1 70 99 43 01 UK +44 (0)20 7806 1967 USA +1 718 354 1385

**AUDIO REPLAY** Available through the numbers below (until November 2, 2008 midnight):

France +33 (0) 1 71 23 02 48 UK +44 (0) 20 7806 1970 USA +1 718 354 1112

Access code 5407125#

### 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). For more information, please visit: <a href="https://www.sanofi-aventis.com">www.sanofi-aventis.com</a>.

## 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 sanofiaventis' 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, 2007. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

### **Contact for Medical Inquiries:**

Please refer to the local sanofi-aventis office.

# **Contact for Media inquiries:**

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