

## **Acomplia (rimonabant) significantly improved glucose control in type 2 diabetes patients treated with insulin**

**Paris, June 10, 2008** - Sanofi-aventis announced today the results of *ARPEGGIO*, the first trial of rimonabant in patients with type 2 Diabetes, not adequately controlled with insulin therapy. These results were presented today at the *68th Scientific Sessions of the American Diabetes Association, in San Francisco*.

Rimonabant 20 mg significantly improved HbA1c (a standard blood measure value that is indicative of a patients' glucose for about two months) by 0.89% from the baseline value, and 0.64% over the control group ( $p < 0.0001$ ). Glucose control was three times more pronounced when rimonabant was added than insulin and lifestyle advice alone.

The 368 type 2 diabetes patients participating to this 11-month trial had been treated with insulin for an average duration of six years prior to entering the study.

*"The ARPEGGIO trial demonstrated that there is still room for significant improvement in diabetic patients who despite several years of standard therapies including insulins, in addition to diet and exercise measures, are not well controlled"*, declared Priscilla L. Hollander, MD, Baylor University Medical Center, Dallas, Texas, USA, and Coordinating Investigator of the study.

Fewer patients in the rimonabant group compared with the control group experienced serious treatment emergent adverse events (16.8% versus 19.3%, respectively). Anxiety was reported in 5% of the patients in the control arm versus 14% in the rimonabant arm. Depression (including depressed mood) was 7.5% in the control group versus 14% in the rimonabant group; most of the patients had a medical history of depression. Similar numbers of severe hypoglycaemia were reported with rimonabant 20 mg/day and control, 8 and 7 cases, respectively.

Diabetes is the fourth leading cause of death by disease globally. Every year, 3.8 million people die from diabetes-related causes.

An increase in hemoglobin A1c of 1 percentage point was generally associated with a 24 % increase in the risk of death from any cause for men (95% CI, 1.14 to 1.34;  $p < 0.001$ ) and a 28% increase for women (CI, 1.06 to 1.32;  $P < 0.001$ ).

### **About Diabetes**

Diabetes is a chronic, progressive widespread disease in which the body reduces or does not produce or properly use insulin – the hormone needed to convert glucose (sugar) into energy. More than 240 million people worldwide are living with the disease. At the same time, more than 40% of patients are not achieving the general blood sugar control standard of A1C  $< 7\%$  recommended by the *American Diabetes Association and the European Association for the Study of Diabetes (ADA/EASD)*. The A1C test reflects average blood glucose levels over a two- to three-month period.



## About ARPEGGIO

ARPEGGIO is part of the phase III b program to study the selective CB1 blocker rimonabant (20 mg daily) versus control in the management of type 2 diabetes and cardiovascular disease. ARPEGGIO was designed to assess the efficacy of rimonabant 20 mg/day as an adjunct therapy in patients with type 2 diabetes who are treated with insulin, yet require further glycaemic control (as measured by HbA1c).

In addition to the significant improvement of HbA1c, when added to insulin for the treatment of type-2 diabetes in ARPEGGIO, rimonabant 20 mg/day showed the following results:

- Rimonabant tripled the number of diabetic patients reaching the 7% HbA1c level recommended by the international medical guidelines (18.4% for the rimonabant group below 7%, and 6.75% patients for the control group), results being statistically significant ( $p=0.0012$ )
- A statistically significant reduction of fasting plasma glucose over control ( $p=0.0193$ ), resulting in a mean treatment difference of  $-0.88$  mmol/l in favour of rimonabant 20 mg/day, consistent with the HbA1c reduction observed
- Demonstrated a statistically significant body weight loss over placebo, resulting in a mean treatment difference of  $-2.56$  kg in favour of rimonabant ( $p<0.0001$ ).

ARPEGGIO, performed in 60 centres, throughout 12 countries, was a double-blind, randomised, parallel-group, fixed-dose, two-arm, controlled trial (rimonabant 20 mg/once daily versus control). Patients had type 2 diabetes treated with insulin (greater than or equal to 30 U/day for at least 4 weeks) with an HbA1c greater than or equal to 7%.

The primary objective of the study was to assess the effect of rimonabant 20 mg/day on HbA1c over a period of 48 weeks (336 days) in patients with type 2 diabetes treated with insulin. Other measures included body weight, waist circumference, serum lipids, glycaemic measures and adverse event data.

## 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 –sanofi-aventis**

*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 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.*