



Diet Drug Acomplia (Rimonabant) Lowers Blood Sugars and Reduces Weight

New study results show patients with an HbA1c level of at least 8.5 when they started taking Acomplia saw their their blood sugar level decrease 1.9 points compared to 0.7 points in patients on a placebo.

Diet drug Acomplia (rimonabant) can significantly improve blood sugar levels in patients with type 2 diabetes while also helping them reduce their weight, according to clinical trial data released December 5th.

The results of the SERENADE (Study Evaluating Rimonabant Efficacy in Drug Naive Diabetic Patients) trial, a six-month study, were announced at the World Diabetes Congress in Cape Town, last week. The SERENADE study involved 278 patients with type 2 diabetes who were not taking any diabetic drugs.

In the study, blood sugar levels of half of the patients on Acomplia fell to below 7 percent -- the target set by the American Diabetes Association for good glucose control -- and the patients taking Acomplia lost almost 15 pounds of weight compared to 6 pounds for those on a placebo.

The trial showed that HbA1c levels (a measure of blood glucose) in patients with a baseline average of 7.9 who took a 20 mg Acomplia pill once daily fell 0.8 percentage points compared to a drop of 0.3 points in those taking a placebo.

Patients with an HbA1c level of at least 8.5 when they started taking Acomplia saw their their blood sugar level decrease 1.9 points compared to 0.7 points in patients on a placebo.

"It is extraordinary that in this last group -- about 25 percent of the participants -- rimonabant was as efficient as several of the best anti-diabetic treatments," said Marc Cluzel, head of international development scientific and medical affairs for drug developer Sanofi-Aventis. In addition, the waist circumference of patients in the trial who were on Acomplia shrank 2.34 inches compared to less than an inch for those on a placebo. Those on Acomplia also saw improvements in their HDL (good) cholesterol and triglycerides (bad fats in the blood).C

The rate of patients leaving the trial before the finish due to adverse effects -- including dizziness, nausea, anxiety, depressed mood and headache -- was 9.4 percent for those on Acomplia and 2.1 percent for those on placebo.

Sanofi's previous one-year diabetes trial, RIO Diabetes, focused on obese and overweight patients with type 2 diabetes who already were being treated with a diabetes drug. In the SERENADE trial, 5 percent of the diabetic patients were not obese or overweight, and none had been on any

diabetes drugs prior to starting on Acomplia.

Acomplia has been approved as a diet pill in the European Union, Mexico and Argentina, but has been bogged down for months for reasons never disclosed by Sanofi-Aventis at the U.S. Food and Drug Administration.

Sanofi aims to position Acomplia, which switches off the same brain circuits that make people hungry when they smoke cannabis, to help treat obesity-related ailments such as heart conditions linked to blood pressure and high cholesterol.

Sanofi clearly intends to ultimately seek to get a diabetes indication added to the weight-loss indication, in hopes that this will bolster prospects that European governments and ultimately U.S. health insurers will pay for what is otherwise a quite expensive prescription drug.

In the news conference, results of the SERENADE trial were presented by Dr. Julio Rosenstock, a Professor of Medicine at the University of Texas Southwestern Medical School in Dallas.

Also participating in the news conference was Dr. André Scheen of the University of Liège in Belgium; Dr. Luc van Gaal, a professor at University Hospital Antwerp in Belgium; and Nick Finner, an honorary consultant in obesity medicine at Addenbrooke's Hospital in Cambridge, United Kingdom.

Announced at the World Diabetes Congress in Cape Town 12-06-06

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FACT:

Type 2 Diabetes Epidemic In Asia: India and China have the greatest numbers of people with diabetes in the world, and by 2025 they could each have 20 million affected individuals. The proportion of people with type 2 diabetes and obesity has increased throughout Asia, and the rate of increase shows no sign of slowing. Type 2 diabetes has now reached epidemic levels in Asia, according to a new survey. India and China have the greatest numbers of people with diabetes in the world, and by 2025 they could each have 20 million affected individuals. In Korea, Indonesia, and Thailand, the prevalence rates of type 2 diabetes have increased three-fold to five-fold during the past 30 years. "Although the prevalence in Asia is currently similar to that in the US, the rate at which diabetes has increased and the likelihood that it will continue to increase at this rate, provide substantial grounds for concern," states Professor Yoon. "The cost of inaction is clear and unacceptable". Lancet Nov 20, 2006

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