Lipitor Provides Greater Benefit Compared to simvastatin in Patients with a History of Heart Attacks Who Have Had Subsequent Cardiovascular Events

Tuesday, November 06, 2007 - 01:00am

(<u>BUSINESS WIRE</u>)--Pfizer announced today that Lipitor® (atorvastatin calcium) Tablets (80 mg) was more effective than simvastatin (20 mg–40 mg) in reducing the risk of multiple cardiovascular events in patients with a history of heart attacks in the Incremental Decreases through Aggressive Lipid Lowering (IDEAL) clinical trial.

Cardiovascular events included heart attack, stroke, and cardiac revascularization procedures such as bypass surgery and angioplasty. The results were presented at the Annual Scientific Sessions of the American Heart Association.

All 8,888 patients enrolled in the trial had a prior heart attack, and 2,546 of them experienced at least one additional cardiovascular event after entering the trial. A new post-hoc analysis (planned after study closed) reported that 1,048 patients had a second cardiovascular event during the course of the trial. In those patients treated with Lipitor, there was a significant 24 percent reduction in relative risk of having that second event than those treated with simvastatin (p<0.0001). The analysis also found that 416 patients had a third event during the course of the trial. In those patients treated with Lipitor there was a significant 19 percent reduction in relative risk of having that third event compared to simvastatin (p=0.035). The overall results of this analysis are even more robust in patients who were more adherent to treatment.

In the original analysis of IDEAL, the primary endpoint of first major coronary event (nonfatal heart attack, coronary heart disease death, cardiac arrest) during the trial was reduced in the Lipitor patients compared to simvastatin patients by 11 percent (p=0.07), which did not reach statistical significance. There was a significant 17 percent (p=0.02) reduction in risk for first nonfatal heart attack and significant 13 percent (p=0.02) reduction in risk of first major cardiovascular events major coronary events and stroke) in patients taking Lipitor.

"Heart attack patients are extremely vulnerable to experiencing even more cardiovascular events. After such an event, the most important task of the treating physician is to reduce the risk of the next cardiovascular event," said Dr. Matti J. Tikkanen, professor of medicine at Helsinki University, and lead author of the analysis. "This analysis showed that Lipitor was more effective than simvastatin in reducing the risk of recurrent cardiovascular events. Our results provide evidence that patients who have already experienced cardiovascular events benefit from Lipitor 80 mg."

The analysis is unique because it evaluated all cardiovascular events that occurred during the five year course of the trial, whereas analyses of most statin trials are usually limited to evaluating the occurrence of the first event only.

"This unique analysis confirmed the benefit of long-term Lipitor 80 mg therapy in patients who have had multiple cardiovascular events," said Dr. Rochelle Chaiken, vice president of Pfizer's Cardiovascular and Metabolic Medical Division. "When treating patients with cardiovascular disease risk it is important to take into account the clinical data for the medication so that the right medicine is chosen for the individual patient."

About Heart Disease and Stroke

This year, approximately 1.2 million Americans will have a first or recurrent coronary attack. Approximately 700,000 will have a new or recurrent stroke. Coronary heart disease is the single leading cause of death in the U.S., while stroke is the third. On average in the U.S., coronary heart disease, including heart attacks, costs \$96,467 in direct costs per patient and a stroke costs \$59,429.

In Europe, cardiovascular disease causes more than 4 million deaths with approximately half all of deaths from coronary heart disease and approximately a quarter from stroke. Cardiovascular disease estimated to cost the EU €169 billion a year.

About Lipitor

Lipitor is the only statin proven to provide a combination of impressive average LDL lowering of 39 percent to 60 percent, significant and proven cardiovascular event reductions, and a well-established safety profile across a broad range of patients.

It is the most prescribed cholesterol-lowering therapy in the world, with nearly 144 million patient-years of experience. Lipitor is supported by an extensive clinical trial program involving more than 400 ongoing and completed trials with more than 80,000 patients.

Important U.S. Prescribing Information

Lipitor is a prescription medication. It is used in patients with multiple risk factors for heart disease such as family history, high blood pressure, age, low HDL ("good" cholesterol) or smoking to reduce the risk of a heart attack and stroke, certain kinds of heart surgery and chest pain.

Lipitor is also used in patients with type 2 diabetes and at least one other risk factor for heart disease such as high blood pressure, smoking or complications of diabetes, including eye disease and protein in urine, to reduce the risk of heart attack and stroke.

Lipitor is used in patients with existing coronary heart disease to reduce the risk of heart attack, stroke, certain kinds of heart surgery, hospitalization for heart failure, and chest pain.

When diet and exercise alone are not enough, Lipitor is used along with a low-fat diet and exercise to lower cholesterol.

Lipitor is not for everyone. It is not for those with liver problems. And it is not for women who are nursing, pregnant or may become pregnant.

Patients taking Lipitor should tell their doctors if they feel any new muscle pain or weakness. This could be a sign of rare but serious muscle side effects. Patients should tell their doctors about all medications they take. This may help avoid serious drug interactions. Doctors should do blood tests to check liver function before and during treatment and may adjust the dose. The most common side effects are gas, constipation, stomach pain and heartburn. They tend to be mild and often go away.

For additional product information, visit <u>www.Lipitor.com</u>.

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