



High-Dose Lipitor Reduced the Risk of Heart Attack and Stroke in Patients with Chronic Kidney Disease

Sunday, April 20, 2008 - 09:22pm

(BUSINESS WIRE)--

Pfizer Inc announced today that Lipitor® (atorvastatin calcium) 80 mg reduced the risk of heart attack and stroke by 32 percent in patients who have heart disease and chronic kidney disease compared with patients taking the 10 mg dose of Lipitor. This analysis, designed and completed following the closure of the five-year Treating to New Targets (TNT) study, was published in the "Journal of the American College of Cardiology."

"People with chronic kidney disease are more likely to die from heart disease than to develop kidney failure," said Dr. James Shepherd, a member of the TNT steering committee and clinical academic consultant, department of pathological biochemistry, University of Glasgow Medical School. "It is critical for us to find new ways to reduce cardiovascular burden in these patients. Intensive statin therapy seems to be at least part of the solution."

The primary endpoint of the TNT study was the reduction of major cardiovascular events, including death from heart disease, non-fatal heart attacks, resuscitated cardiac arrest, and fatal or non-fatal strokes. This sub-analysis studied 3,107 patients with moderate to severe chronic kidney disease, as defined using a standard measure of kidney function. The efficacy results in this analysis were primarily driven by reductions in heart attack and stroke. Both doses of Lipitor (80 mg and 10 mg) were well tolerated. Lipitor 80 mg is not a starting dose. The safety of Lipitor 80 mg in patients with chronic kidney disease was similar to that reported for the overall TNT population, with no unexpected safety

concerns identified.

“The results of this analysis complement the large body of evidence from multiple clinical trials demonstrating the cardiovascular benefits of Lipitor,” said Halit Bander, Ph.D. senior director of Pfizer’s global cardiovascular metabolic medical team.

About Chronic Kidney Disease

An estimated 26 million Americans and 50 million people worldwide have chronic kidney disease, or permanent kidney damage due to injury or disease. Patients with chronic kidney disease do not effectively filter toxins from the blood. When chronic kidney disease progresses to kidney failure, either dialysis or a kidney transplant is needed. Chronic kidney disease recently has been recognized as an important risk factor for cardiovascular disease, the leading cause of death and illness in patients with kidney disease.

About the TNT Study

The TNT study was a landmark investigator-led trial coordinated by an independent steering committee and funded by Pfizer. It was the largest study to date evaluating the efficacy and safety of Lipitor 80 mg. The study enrolled 10,001 men and women with coronary heart disease aged 35 years to 75 years in 14 countries and followed them for an average of five years. The safety of Lipitor 80 mg in patients with chronic kidney disease was similar to that reported for the overall TNT population, with no unexpected safety concerns identified.

About Lipitor

Lipitor is the only statin proven to provide a combination of impressive average LDL (“bad” cholesterol) 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 151 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, stroke, certain types 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 www.Lipitor.com.

Pfizer IncVanessa Aristide, 212-733-3784Rebecca Hamm, 212-733-8811Jennifer Davis,
212-733-0717