

Intensive Lipitor Therapy Was Associated With Reduced Risk Of Cardiovascular Events In Two High-Risk Patient Groups

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ATLANTA--([BUSINESS WIRE](#))--Lipitor[®] (atorvastatin calcium) 80 mg was associated with a significantly reduced risk of major cardiovascular events compared with Lipitor 10 mg among patients with both coronary heart disease (CHD) and chronic kidney disease (CKD) who were obese or had metabolic syndrome. These data, from two sub-analyses of the Treating to New Targets (TNT) trial that were designed and completed following the completion of TNT, were presented today at the 59th Annual Scientific Session of the American College of Cardiology (ACC) in Atlanta, Ga.

“Nearly 26 million Americans suffer from CKD, which is often associated with co-morbidities – such as heart disease, metabolic syndrome or obesity – that can increase risk for heart attack and stroke,” said Dr. Prakash Deedwania, professor of Medicine, UCSF School of Medicine, San Francisco, CA and Chief, Cardiology Section, VACCHCS/UCSF Program, Fresno, CA. “The new data presented at ACC demonstrate that Lipitor 80 mg may help prevent cardiovascular events in these high-risk patients.”

According to the new analyses, for patients with both CHD and CKD, being obese or having metabolic syndrome may further increase their risk for cardiovascular events.

In one sub-analysis, which looked at the 1,859 patients in TNT who had CHD, CKD and metabolic syndrome, Lipitor 80 mg was associated with a 35 percent reduction in the risk of major cardiovascular events compared with Lipitor 10 mg. In a separate sub-analysis of the 954 patients in TNT with CHD, CKD and obesity, Lipitor 80 mg was associated with a 33 percent reduction in the risk of major cardiovascular events compared with Lipitor 10 mg. For both sub-analyses, major cardiovascular events included a combined endpoint of death from heart disease, non-fatal heart attack, resuscitated cardiac arrest and fatal or non-fatal stroke.

The safety of Lipitor in these patient sub-sets was consistent with that in the overall TNT trial. Lipitor is not approved for the treatment of CKD, obesity or metabolic syndrome.

About the TNT Study

The original TNT study was an investigator-led trial coordinated by an independent steering committee and funded by Pfizer. 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. After an eight week run-in on Lipitor 10 mg, patients were randomized to receive either Lipitor 10 mg or Lipitor 80 mg. Primary study results were published in *The New England Journal of Medicine* in 2005.

The primary endpoint of the original TNT study was the time to occurrence of a first major cardiovascular event, defined as death from heart disease, non-fatal heart attack, resuscitated cardiac arrest, or fatal or non-fatal stroke.

Lipitor 80 mg is not a starting dose. Lipitor is not approved in all countries to reduce the risk of cardiovascular events in patients with existing heart disease.

Throughout the TNT study, Lipitor was generally well tolerated.

About Obesity and Metabolic Syndrome

Obesity, defined as having a body mass index of 30 or higher, affects more than one-third of the U.S. adult population, according to the latest National Health and Nutrition Examination Survey. Obesity is now recognized by the American Heart Association (AHA) as a major risk factor for CHD, which can lead to heart attack. Obesity is also associated with metabolic syndrome, which the AHA defines as the presence of three or more related health factors, including insulin resistance, high waist circumference, low HDL cholesterol levels and high blood pressure and triglycerides. Patients with metabolic syndrome are at increased risk for CHD and other diseases related to plaque build-ups in artery walls.

About Chronic Kidney Disease

Patients with CKD do not effectively filter toxins from the blood. When CKD progresses to kidney failure, either dialysis or a kidney transplant is needed. CKD has been recognized as an important independent predictor of cardiovascular risk, and patients with CKD are more likely to die from a cardiovascular event than to reach end-stage renal disease.

Important U.S. Prescribing Information

Lipitor is a prescription medicine that is used along with a low-fat diet. It lowers the LDL ("bad" cholesterol) and triglycerides in your blood. It can raise your HDL ("good" cholesterol) as well. Lipitor can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as age, smoking, high blood pressure, low HDL, or family history of early heart disease.

Lipitor can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as diabetic eye or kidney problems, smoking, or high blood pressure.

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 doctor 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 doctor about all medications they take. This may help avoid serious drug interactions. Doctors should do blood tests to check your liver function before and during treatment and may adjust the dose. Common side effects are diarrhea, upset stomach, muscle and joint pain, and changes in some blood tests.

For additional product information, visit www.Lipitor.com.

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