# New Analysis Showed That High Dose Lipitor Can Reduce the Risk of Cardiovascular Events in Bypass Surgery Patients

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(<u>BUSINESS WIRE</u>)--Pfizer Inc announced today that Lipitor® (atorvastatin calcium) 80 mg significantly reduced the risk of major cardiovascular events, including heart attack and stroke, by 27 percent in patients with heart disease who had previous coronary bypass surgery 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."

Intensive Lipitor therapy also provided a significant 30 percent reduction in the need for either repeat coronary bypass surgery or angioplasty, another type of interventional heart surgery, compared with Lipitor 10 mg.

Each year in the U.S., approximately 470,000 bypass surgeries are performed on 270,000 people. Patients in the TNT study who had undergone previous bypass surgery had a much higher likelihood of cardiovascular events than those who did not have prior bypass surgery. This especially high risk population tends to be under-treated with lipid-lowering therapy.

"Patients may be under the impression that once they have had coronary bypass surgery, they are no longer at high risk for heart attacks and strokes," said Dr. Rochelle Chaiken, vice president of Pfizer's global cardiovascular and metabolic medical team. "Although these patients continue to be at an increased risk for major cardiovascular events and repeat heart surgery, statins are considerably underused. This analysis highlights not only the importance of treating, but also treating aggressively with Lipitor 80 mg."

Both doses of Lipitor (80 mg and 10 mg) were well-tolerated in patients with prior coronary bypass surgery, and the safety profile of Lipitor 80 mg was comparable to Lipitor 10 mg, a finding that was consistent with the overall TNT population.

## **About the TNT Study**

The TNT study was an investigator-led trial coordinated by an independent steering committee and funded by Pfizer. The primary endpoint 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.

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. In this analysis, 4,654 patients who had previous coronary bypass surgery were compared with 5,347 patients who did not. Lipitor 80 mg is not a starting dose.

### **About Coronary Bypass Surgery**

Coronary bypass surgery is a procedure in which damaged sections of the coronary arteries (arteries that bring blood to the heart muscle) are replaced with healthy blood vessel segments. The surgery reroutes, or "bypasses," blood around clogged arteries to improve blood flow and oxygen to the heart.

This procedure is done because arteries that bring blood to the heart muscle can become clogged by plaque (a buildup of fat, cholesterol and other substances). This can slow or stop blood flow through the heart's blood vessels, leading to chest pain or a heart attack. Increasing blood flow to the heart muscle can relieve chest pain and reduce the risk of heart attack.

#### **About Angioplasty**

Angioplasty is a type of interventional heart surgery which encompasses a variety of procedures used to treat patients with diseased arteries of the heart, such as:

- Chest pain caused by a build-up of fats and cholesterol.
- Other substances from the blood (referred to as plaque) that can reduce blood flow to a near trickle.
- A heart attack caused by a large blood clot that completely blocks the artery.

Typically, angioplasty is performed by threading a slender balloon-tipped tube – a catheter – from an artery in the groin to a trouble spot in an artery of the heart. The balloon is inflated, compressing the plaque and widening the narrowed coronary artery so that blood can flow more easily. This is often accompanied by inserting an expandable metal stent (a small mesh tube) to keep the artery open.

## **About Lipitor**

Only Lipitor offers these three benefits important in a statin: FDA approval to reduce the risk of heart attacks, strokes and other cardiovascular events in patients with or without heart disease; the ability to reduce "bad" cholesterol (LDL) by 39 percent to 60 percent; 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 a 15-year 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 heart attack, stroke, certain kinds of heart surgery, and chest pain.

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.

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.

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.

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