## Adding Lipitor Early to Effective Blood Pressure Treatment Provided a Significant Reduction in Heart Attacks or Deaths from Heart Attacks over Five Years

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(<u>BUSINESS WIRE</u>)--The early addition of Lipitor® (atorvastatin calcium) Tablets to effective blood pressure lowering treatment maintained a significant 36 percent reduction in the relative risk of fatal or non-fatal heart attacks over five years, according to a new analysis.

This was a post-hoc analysis (designed and completed following the closure of the trial) of the lipid-lowering arm of the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT-LLA) follow-up period. A majority of patients who were treated with Lipitor or placebo during a three-year study went on to receive Lipitor during two years of post-study follow up. At the start of the study, patients had high blood pressure and additional cardiovascular risk factors but no coronary heart disease. ASCOT-LLA is one of the first studies to explore the benefit of controlling more than one cardiovascular risk factor at a time.

"These important results show that early initiation of Lipitor with an effective blood pressure lowering drug regimen may have significant clinical implications for reducing the risk of heart attacks," said Professor Peter Sever, study principal investigator, professor of clinical pharmacology and therapeutics, International Centre for Circulatory Health at London's Imperial College. "It is vital that physicians use the right combination of treatments from the start to maximize the reduction in the risk of heart attacks and coronary heart disease death."

The results were published online in the European Heart Journal.

"Patients with high blood pressure and other risk factors for cardiovascular disease are usually treated with blood pressure lowering medications first," said Professor Bryan Williams, professor of medicine, University Hospitals NHS Trust, Leicester, United Kingdom, and chairman of the British Hypertension Society Guidelines working party.

"It is important to note, however, that many people with high blood pressure are also at sufficient risk of cardiovascular disease to benefit from statin therapy," he said. "Even if patients are prescribed statins in this context, they are generally only treated with statins after lifestyle modifications have failed.

"This study highlights the importance of initiating medical treatment for both blood pressure and cholesterol as soon as possible, and raises questions about medical guidelines that do not focus on early intensive treatment of multiple risk factors, notably blood pressure and cholesterol, in patients with moderate cardiac risk," he said.

Pfizer offers physicians and patients the option of Lipitor or a combination medication known as Caduet® (amlodipine besylate/atorvastatin calcium) that includes Lipitor and Norvasc® (amlodipine besylate).

## About the study

The ASCOT study was one of the largest hypertension trials ever conducted with 19,342 patients in Europe. It compared the calcium channel blocker anti-hypertensive Norvasc based regimen versus a beta-blocker based regimen in reducing cardiac events in patients with high blood pressure and additional cardiovascular risk factors but without coronary heart disease.

Patients in ASCOT-LLA had normal to mildly elevated cholesterol levels (n=10,000), were not candidates for lipid-lowering treatment at the time of the study initiation, and received Lipitor 10 mg or placebo at the outset of the trial.

The ASCOT-LLA part of the trial was expected to last five years, but was stopped early after three years due to a highly significant 36 percent lower risk of death from heart disease and non-fatal heart attack in patients treated with Lipitor versus patients taking placebo.

At the end of the follow-up period, LDL-C levels were similar in both groups as a result of Lipitor treatment and the average blood pressure level was significantly reduced from 164/95 mmHg to 137/78 mmHg with the blood pressure lowering therapy.

Funded by Pfizer, ASCOT was an investigator-led trial coordinated by an independent steering committee.

## **Important U.S. Prescribing Information for Lipitor**

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 www.Lipitor.com.

## **Important U.S. Prescribing Information for Caduet**

Caduet is a prescription drug that combines 2 medicines, Norvasc and Lipitor. Norvasc is used to treat high blood pressure (hypertension), chest pain (angina), or blocked arteries of the heart (coronary artery disease); Lipitor is used along with diet and exercise to lower high cholesterol. It is also used to lower the risk of heart attack and stroke in people with multiple risk factors for heart disease – such as family history, high blood pressure, age, low HDL-C, or smoking.

Caduet is not for everyone. It is not for those with liver problems. And it is not for women who are nursing, are pregnant or may become pregnant. If you take Caduet, tell your doctor if you feel any new muscle pain or weakness. This could be a sign of rare but serious muscle side effects.

Tell your doctor about all of the medicines you take. This may help avoid serious drug interactions. Your doctor should do blood tests to check your liver function before and during treatment and may adjust your dose. If you have any heart problems, be sure to tell your doctor. The most common side effects are edema, headache, and dizziness. They tend to be mild and often go away.

Caduet is one of many options for treating high blood pressure and high cholesterol, in addition to diet and exercise, that you or your doctor can consider.

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

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