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Post-Stroke Patients Treated with Lipitor Demonstrated Significant Improvement or Stabilization of Kidney Function

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(BUSINESS WIRE)--Pfizer announced today that post-stroke or mini-stroke patients treated with Lipitor® (atorvastatin calcium) Tablets 80 mg had stabilization or improvement in kidney function. These results were demonstrated in patients with or without chronic kidney disease, metabolic syndrome or type 2 diabetes. This post-hoc analysis of the landmark Stroke Prevention by Aggressive Reduction of Cholesterol Levels (SPARCL) study, was presented at the Annual Scientific Sessions of the American Heart Association.

About 700,000 Americans and 1.1 million Europeans suffer from a stroke or mini-stroke annually. Data from the SPARCL study show that stroke patients with type 2 diabetes, metabolic syndrome or chronic kidney disease are at increased risk of additional cardiovascular events, compared to patients without these conditions.

Analysis of Changes in Kidney Function in the SPARCL study

In this new post-hoc analysis (planned after the study closed) of the SPARCL study, kidney function was evaluated by estimated glomerular filtration rate (eGFR, mL/min/1.73m^2), a standard test to measure how well the kidneys function.

Post-stroke or mini-stroke patients without chronic kidney disease, with chronic kidney disease and with metabolic syndrome treated with Lipitor 80 mg had significantly improved kidney function compared to placebo.

In post-stroke or mini-stroke patients with type 2 diabetes, those treated with Lipitor demonstrated stabilized kidney function, while patients receiving placebo had significantly declined kidney function during the trial.

“These results are especially significant for post-stroke diabetic patients because they are more likely to develop progressive kidney disease,” said Dr. Vito Campese, chief of the division of nephrology/hypertension at the University of Southern California. “With Lipitor we were able to stabilize patients’ kidney function, and given the established relationship between progressive kidney disease and cardiovascular outcome, this may contribute to reducing cardiovascular events. These results are similar to findings from the Treating to New Targets study which found that patients with coronary heart disease treated with Lipitor had stabilized and even improved kidney function.”

Post-stroke or mini-stroke patients treated with Lipitor 80 mg had:

- Significantly improved kidney function compared to placebo in those 2,671 patients without chronic kidney disease (change in eGFR during the trial 2.22 vs. 0.22 mL/min/1.73m^2, $p<0.0001$)
- Significantly improved kidney function compared to placebo in those 1,315 patients with chronic kidney disease (change in eGFR during the trial of 3.15 vs. 1.82 mL/min/1.73m^2,$p=0.017$)

- Significantly improved kidney function, measured as change in estimated glomerular filtration rate, compared to placebo in those 593 patients with metabolic syndrome (change in eGFR during the trial of 2.39 vs. 0.24 mL/min/1.73m^2, respectively p=0.012)
- Stabilized kidney function compared to placebo in those 730 patients with type 2 diabetes (change in eGFR of -0.735 vs. -4.016 mL/min/1.73m^2, p<0.001).

Additional Analysis of Cardiovascular Outcomes in Patients with Chronic Kidney Disease

In the SPARCL study, patients with chronic kidney disease had higher risk of stroke (27 percent) or major coronary events (70 percent) compared to patients without chronic kidney disease.

- In patients with chronic kidney disease, Lipitor 80 mg significantly reduced the risk of major coronary events (including cardiovascular death, non-fatal heart attack, resuscitated cardiac arrest) by 39 percent compared to placebo, however there was no difference in the risk of stroke compared to placebo

About the SPARCL Study

The SPARCL study (n=4,731), published in the *New England Journal of Medicine* in 2006, is the only study to date evaluating the benefits of a statin solely in patients with a prior stroke or mini-stroke. Lipitor 80 mg reduced the risk of an additional stroke by 16 percent and major coronary events by 35 percent compared with placebo.

In a post-hoc analysis of the SPARCL trial, there was a higher incidence of hemorrhagic stroke in patients taking Lipitor 80 mg compared with patients taking placebo. Patients with prior hemorrhagic stroke at study entry appeared to be at an increased risk of hemorrhagic stroke.

In SPARCL, Lipitor was well-tolerated. The rate of side effects such as elevated liver enzymes, muscle weakness or rhabdomyolysis were low and consistent with the known safety profile.

About Stroke, Kidney Disease and Cardiovascular Disease

Cardiovascular disease is the number one cause of death globally and is projected to remain the leading cause of death. Stroke is the third leading cause of death and the leading cause of adult disability in the United States and industrialized European nations. About 700,000 Americans and 1.1 million Europeans suffer from a stroke or mini-stroke annually. The World Health Organization estimates that 15 million people each year suffer strokes and 5 million are left permanently disabled.

It is estimated that 4.5 million people in Europe have chronic renal disorders, with kidney diseases representing a leading cause of mortality. Chronic kidney disease has been recognized as an important risk factor for cardiovascular disease. Various illnesses may lead to chronic kidney disease, including high blood pressure and diabetes, the number-one cause of kidney failure.

About Lipitor

Lipitor is the most extensively studied and 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, 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.

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