Patients Taking Lipitor Had a Significantly Reduced Risk of Cardiovascular Events Compared with Patients Taking Simvastatin, New Observational Study Shows

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(<u>BUSINESS WIRE</u>)--Pfizer announced the results of an observational study that showed patients taking Lipitor (atorvastatin calcium) had a significant 13 percent reduction in the relative risk of experiencing a cardiovascular event compared with patients taking simvastatin (Zocor) therapy. The patients in this study did not have evident cardiovascular disease and were newly initiated on either treatment. This study was performed in conjunction with HealthCore, WellPoint's health outcomes research subsidiary. Results of this study, from one of the largest U.S. managed care claims databases with more than 219,000 adult patients, were published in the December issue of *Mayo Clinic Proceedings*.

The study examined data for patients 18-64 years old who had no prior statin use or medical claims related to cardiovascular disease in the 12 months preceding initiation of statin therapy. The average doses in the study were 29 mg of simvastatin and 17 mg of Lipitor.

"Observational data such as this, which reflect the use of medicines in real-world clinical practice rather than in a controlled trial setting, may help healthcare providers and managed care companies improve clinical outcomes for patients," said Terry A. Jacobson, Professor of Medicine, Emory University, and director of the Office of Health Promotion and Disease Prevention, Grady Health Systems. "The data suggests that statins with greater potency may result in greater cardiovascular risk reductions. Economic assessments should be performed to determine the potential impact of this study on cost of care to patients."

In addition to the significant reduction in the risk of overall cardiovascular events, individual event rates of secondary endpoints, first heart attack and hospitalizations for heart failure, were significantly lower for patients initiating Lipitor compared with patients initiating simvastatin. There was no significant difference between the groups for the secondary endpoints of stroke, revascularization surgery or peripheral vascular disease.

"This latest analysis adds to the wealth of real-world data from a number of different medical database analyses that suggest that patients who are treated with Lipitor may have a reduced risk of experiencing a cardiovascular event compared with patients who use simvastatin," said Dr. Michael Berelowitz, senior vice president of Pfizer's global medical division. "Findings such as these should be taken into account by those who may assume that medicines in a therapeutic class are interchangeable and provide similar outcomes."

As with all observational studies, the study is subject to certain limitations and the findings should be regarded as hypothesis generating.

About the study

This is one of the largest observational studies to date to examine cardiovascular outcomes in patients without clinically evident cardiovascular disease treated with different statins in routine clinical practice.

The retrospective analysis examined administrative claims for statin prescriptions filed between January, 2003 and December, 2005. The longer mean treatment duration of patients who took Lipitor versus simvastatin (nine and seven months, respectively) might have impacted the difference in cardiovascular event reduction.

A cardiovascular event was defined as the first inpatient or emergency room admission for heart disease, heart attack, angina (chest pain), certain heart surgeries, peripheral vascular disease, aortic aneurysm (swelling of the aorta), stroke and transient ischemic attack.

Since patients were not randomly assigned to each group, the two treatment arms were adjusted based on certain risk factors, such as age, gender and co-morbidities, and statistical adjustments were used to address residual imbalances. LDL values prior to and after treatment were only available for approximately five percent of the patients and this was not adjusted for in the analysis.

The results of this study complement the large body of evidence from multiple clinical trials demonstrating the cardiovascular benefits of Lipitor in patients without heart disease and are in alignment with findings from previously published observational studies.

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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