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Lipitor Significantly Reduced hsCRP Levels in Patients with Stable Coronary Artery Disease, According to New Study

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Intensive Lipitor Therapy Significantly Reduced hsCRP Levels Further Than Low-Dose Lipitor

NEW YORK--(BUSINESS WIRE)--Patients treated with Lipitor® (atorvastatin calcium) 80 mg had a significant 55 percent reduction in levels of high-sensitivity C-reactive protein (hsCRP), while those taking Lipitor 10 mg had a significant 21 percent reduction in hsCRP levels at the end of 26 weeks compared to baseline, according to the results from the primary endpoint of a new study. Patients in this study had stable coronary artery disease, normal to mildly elevated cholesterol levels and chronic low-grade inflammation as indicated by elevated levels of hsCRP, which studies suggest may play a role in determining cardiovascular risk. The findings, from the Comparative Atorvastatin Pleiotropic effects (CAP) study, were recently published in *Clinical Therapeutics*.

“These findings support results from prior clinical trials suggesting that, in addition to lowering LDL cholesterol levels, Lipitor may help reduce hsCRP, which reflects the systemic inflammation that might contribute to increased risk for cardiovascular events,” said Dr. Jean Davignon, director of the hyperlipidemia and atherosclerosis research group at the Clinical Research Institute of Montreal and a principal investigator of the trial. “Even more encouraging was the fact that further reductions in hsCRP were observed with intensive Lipitor therapy versus a lower dose.”

The CAP trial was a prospective, randomized, double-blind, 26-week study designed to examine the effects of low-dose versus high-dose Lipitor on hsCRP levels in men and women under the age of 80 with stable coronary artery disease, normal to mildly elevated cholesterol levels and chronic low-grade inflammation as indicated by elevated levels of hsCRP. The mean baseline hsCRP concentration was 3.1 mg/L and 3.6 mg/L in the Lipitor 10 mg and Lipitor 80 mg treatment groups, respectively. Coronary artery disease was defined by at least one of the following: history of heart attack, stable angina, coronary narrowing of at least 50 percent, history of unstable angina and history of coronary artery bypass grafting or coronary angioplasty.

A total of 340 patients were treated with either low-dose Lipitor 10 mg or intensive Lipitor 80 mg therapy. The primary endpoint of the study was the percent change in hsCRP after 26 weeks of treatment with Lipitor 10 mg or 80 mg. Comparisons of hsCRP levels at five weeks were pre-determined secondary endpoints.

After five weeks of therapy, patients treated with Lipitor 10 mg had a significant 25 percent reduction in hsCRP levels compared to baseline, and hsCRP levels remained stable at study end (21 percent reduction). Patients treated with Lipitor 80 mg for five weeks had a significant 36 percent reduction in hsCRP levels compared to baseline. These levels were reduced further at study end to a total reduction of 55 percent. The effects of Lipitor on changes in hsCRP levels were dose dependent; high-dose Lipitor was associated with significantly greater reductions.

Reductions in hsCRP were largely independent of the significant reductions in LDL cholesterol that were also observed in both treatment groups. At 26 weeks, those treated with Lipitor 80 mg had significantly greater reductions in LDL cholesterol compared to those who received Lipitor 10 mg (51 percent versus 35 percent, respectively).

Both doses of Lipitor (10 mg and 80 mg) were generally well tolerated.

The prevalence of adverse events considered by the investigators to be treatment-related was 8.2 percent in the 10 mg group and 11.8 percent in the 80 mg group. The most common adverse events, reported with an incidence greater than 1 percent in either the 10 mg or 80 mg group, were asthenia (1.8 percent and 1.8 percent, respectively), increased creatinine kinase (1.8 percent and 0.6 percent), myalgia (1.2 percent and 2.4 percent), constipation (1.2 percent and 1.8 percent), increased aspartate aminotransferase (0 percent and 1.2 percent) and insomnia (0 percent and 1.2 percent). The majority of adverse events in both treatment groups were mild to moderate in intensity, with only 1.2 percent of patients in each group reporting severe side effects.

The study was sponsored by Pfizer and led by a joint Canadian/French steering committee. Patients were recruited from 65 sites in seven countries.

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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