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Two New Imaging Studies Show Higher Dose Lipitor Stopped the Progression of Atherosclerosis

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New Results Build on Previous Data that Lipitor is the Only Statin to Show an Impact in Head-To-Head Imaging Trials Separate Analysis Shows Lipitor Cuts the Risk of Coronary Events by Half in Recurrent Stroke Patients

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(BUSINESS WIRE)--Pfizer said today that results from two new imaging trials showed that higher dose Lipitor stopped the progression of atherosclerosis in patients with coronary heart disease or familial hypercholesterolemia (FH). The trials, which were designed to investigate the efficacy of the former investigational compound torcetrapib in combination with Lipitor compared to Lipitor alone, were presented today at the annual meeting of the American College of Cardiology.

In the Lipitor arm of the ILLUSTRATE and RADIANCE 1 trials, patients took an average Lipitor dose of 23 mg and 56 mg respectively and experienced halting of the progression of atherosclerosis. In the ILLUSTRATE trial, treatment with Lipitor resulted in plaque regression in the most diseased part of the coronary artery. In contrast in the Lipitor arm of RADIANCE 2 patients took a low average Lipitor dose of 13 mg and progression of atherosclerosis was observed.

“From a clinical perspective, what is remarkable in these studies is that Lipitor was able to stop the progression of disease, including the most difficult to treat FH patients studied in RADIANCE 1,” said Professor John Kastelein, lead investigator for two of the trials, and professor of medicine and chairman of vascular medicine at the Academic Medical Center in Amsterdam. “These trials build on the effects seen with Lipitor in numerous imaging trials.”

Lipitor is the only statin to have been studied in head-to-head imaging trials. In the ASAP and ARBITER trials, which measured changes in cIMT, high-risk patients who took Lipitor 80 mg experienced regression in atherosclerosis compared with patients who took other statins. In the REVERSAL trial, Lipitor patients experienced a halting of plaque progression compared with pravastatin, and Lipitor patients experienced a significant reduction in the plaque volume in the most diseased segments compared with pravastatin as measured by IVUS.

According to Dr Michael Berelowitz, Senior Vice President of Pfizer’s global medical division, “These results support previous studies where higher doses of Lipitor have demonstrated impact on atherosclerosis. However, while imaging findings are scientifically interesting, we know that physicians make clinical decisions based on proven cardiovascular outcomes.”

Lipitor Offers Remarkable Benefit for Stroke Patients

In a new separate analysis from a landmark clinical trial known as the Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL), patients without heart disease, who had suffered a recurrent stroke or mini-stroke during the trial and took Lipitor 80 mg had a significant 53 percent reduction in the risk of major coronary events (death from cardiac causes, heart attack, or resuscitation after cardiac arrest).

"This is the first time a statin has been shown to provide coronary benefit for patients with recent stroke or mini-stroke," said Professor Henrik Sillesen, chairman of the department of vascular surgery at the University of Copenhagen in Denmark. "What is impressive is the magnitude of benefit seen with Lipitor in these high risk patients. The results show that aggressive lipid lowering with Lipitor addresses an unmet medical need."

“This adds to the wealth of scientific evidence which has consistently shown improved cardiovascular outcomes in a broad range of patients. Lipitor is the only statin that offers a unique and robust body of evidence that includes proven reductions in heart attacks and stroke, impressive average LDL lowering of 39 to 60 percent, and an established safety profile across a broad range of patients,” said Dr Berelowitz.

Summary of Imaging Trials Results for the Lipitor Arm

The three, two-year clinical trials, involving over 2,800 patients were designed to investigate the efficacy of torcetrapib in combination with Lipitor compared to Lipitor alone on the progression of atherosclerosis as measured by coronary intravascular ultrasound (IVUS) or carotid B-Mode ultrasound. IVUS is a relatively new, three-dimensional method of imaging to measure the total plaque volume in a cross-section of the coronary artery wall over the length of the vessel. Carotid ultrasound measures the thickness between the inner and middle layers of the carotid artery wall (IMT). All three trials had a run-in phase in which all patients were treated with Lipitor and patients’ doses were titrated until individual LDL-C goals were reached. Patients were then randomized to either a combination of torcetrapib and Lipitor or Lipitor alone. Patients remained on the same dose of Lipitor for the duration of the two year study.

ILLUSTRATE

In patients with coronary heart disease randomized to Lipitor, progression of atherosclerosis was halted. Patients took an average dose of 23 mg of Lipitor (n=446). There was no significant change from baseline in percent atheroma volume (0.19%) and there was a significant regression of plaque build-up in the most diseased segment of the coronary artery (-3.3mm^3).

RADIANCE 1

In patients with a genetic condition known as familial hypercholesterolemia resulting in extremely high LDL levels randomized to Lipitor, progression of atherosclerosis was halted. Patients took an average dose of 56 mg of Lipitor (n=427). There was no significant change from baseline in the IMT of the 12 carotid segments (0.0053mm/yr) nor in the common carotid artery (-0.0014mm/yr).

RADIANCE 2

Patients with high LDL and high triglycerides randomized to Lipitor experienced a progression of atherosclerosis. Patients took an average low, 13 mg dose of Lipitor (n=344). There was a significant change from baseline in the IMT of the 12 carotid segments (0.0296mm/yr) and a small but statistically significant change in the common carotid artery (0.0076mm/yr).

About the Overall SPARCL Study

The SPARCL study, 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 (n=4,731). 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.

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. Lipitor is not indicated for atherosclerosis.

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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