Novel Biomarkers, Including CRP, Did Not Predict Risk Of Cardiovascular Events In Patients With Heart Disease Who Were Treated With A Statin

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LDL Cholesterol Levels Remain Among the Best Predictors of Cardiovascular Events, According to a New Analysis of the Pfizer-Sponsored TNT Clinical Trial

(BUSINESS WIRE)--For patients with established heart disease who were treated with a statin, 18 novel biomarkers including C-reactive protein (CRP) did not predict future cardiovascular events such as heart attack and stroke, according to results of an analysis presented today at the 2009 European Society of Cardiology Congress in Barcelona, Spain. By contrast, traditional lipid risk factors were strong predictors of cardiovascular events. The findings are based on a new post hoc sub-analysis of patients treated with Lipitor® (atorvastatin calcium) in the five-year Treating to New Targets (TNT) study.

These results follow on the heels of findings published recently in the Journal of the American Medical Association suggesting that novel biomarkers such as CRP provided minimal additional value beyond conventional risk factors for assessing cardiovascular risk. “For patients with stable coronary disease who were already on statin therapy, novel biomarkers do not appear to add predictive value over traditional lipid markers such as LDL cholesterol,” said Dr. John LaRosa, president and professor of medicine at the State University of New York Downstate Medical Center in Brooklyn, NY, and chair of the TNT steering committee. “Today’s analysis adds to the body of evidence that ‘traditional’ risk

factors, including elevated blood cholesterol and blood pressure, as well as cigarette smoking, remain the highest priority targets for reducing cardiovascular risk. Drugs such as atorvastatin, used in this study, have demonstrated effectiveness in accomplishing this goal."

To determine whether levels of biomarkers or lipids after an eight-week run-in period on Lipitor 10 mg were predictive of an increased risk for future cardiovascular events, a nested case-control analysis of the TNT trial was performed. Patients included in the TNT trial had coronary heart disease and were treated with Lipitor. For the analysis, data for 507 patients who experienced a primary event (defined as cardiac death, heart attack, stroke or resuscitated cardiac arrest) were compared with data for 1020 patients who did not experience events.

The 18 novel biomarkers were not predictive of risk for future cardiovascular events in patients with stable coronary heart disease already on statin therapy. Higher levels of LDL cholesterol and triglycerides and lower levels of HDL cholesterol, however, were each strongly and significantly predictive of risk for future events.

About the TNT Study

The original TNT study was an investigator-led trial coordinated by an independent steering committee and funded by Pfizer. The study enrolled 10,001 men and women with coronary heart disease aged 35 years to 75 years in 14 countries and followed them for an average of five years. After an eight week run-in on Lipitor 10 mg, patients were randomized to receive either Lipitor 10 mg or Lipitor 80 mg. Primary study results were published in The New England Journal of Medicine in 2005.

The primary endpoint of the original TNT study was the time to occurrence of a first major cardiovascular event, defined as death from heart disease, non-fatal heart attack, resuscitated cardiac arrest, or fatal or non-fatal stroke.

Lipitor 80 mg is not a starting dose. Lipitor is not approved in all countries to reduce the risk of cardiovascular events in patients with existing heart disease.

Throughout the TNT study, Lipitor was generally well tolerated.

Important U.S. Prescribing Information

LIPITOR is a prescription medicine that is used along with a low-fat diet. It lowers the LDL ("bad" cholesterol) and triglycerides in your blood. It can raise your HDL ("good" cholesterol) as well. LIPITOR can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as age, smoking, high blood pressure, low HDL, or family history of early heart disease.

LIPITOR can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as diabetic eye or kidney problems, smoking, or high blood pressure.

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 doctor 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 doctor about all medications they take. This may help avoid serious drug interactions. Doctors should do blood tests to check your liver function before and during treatment and may adjust the dose. Common side effects are diarrhea, upset stomach, muscle and joint pain, and changes in some blood tests.

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

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