Caduet Reduces 10-Year Calculated Risk Of Coronary Heart Disease, Fatal Cardiovascular Disease

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(BUSINESS WIRE)--Caduet® (amlodipine besylate/atorvastatin calcium) was associated with a significantly reduced calculated 10-year risk of coronary heart disease (CHD) based on a Framingham risk assessment model. In addition, Caduet was shown to reduce calculated fatal cardiovascular disease (CVD) risk, as a secondary trial endpoint based on the SCORE risk assessment model. The Framingham and SCORE risk assessment models are widely used in the U.S. and EU, respectively. These data from the CRUCIAL (Cluster Randomized Usual Care vs. Caduet Investigation Assessing Long-term Risk) trial were presented yesterday at the 20th Scientific Meeting of the European Society of Hypertension (ESH) in Oslo, Norway.

“The data presented at ESH are important because they show the potential benefit of Caduet, which combines blood pressure and cholesterol-lowering medications in a single pill, over usual care in a real-life clinical setting,” said Professor José Zamorano of the Hospital Clinico San Carlos, Madrid, Spain, and chair of the CRUCIAL steering committee. “The findings suggest that Caduet may have the potential to significantly reduce CV risk in patients with two of the most common modifiable risk factors that contribute to cardiovascular disease: high cholesterol and high blood pressure.”

The CRUCIAL trial randomized 136 physicians to either Caduet or usual care. The physicians then treated a total of 1,461 men and women aged 35-79 who had

hypertension, three or more cardiovascular risk factors, no CHD, and total cholesterol ≤6.5 mmol/l (250 mg/dl) with their assigned therapy. Usual care included physicians' choice of any locally approved medications for lowering blood pressure or cholesterol, including but not limited to amlodipine and atorvastatin, prescribed according to local clinical practice. Physicians in the Caduet arm treated eligible patients with Caduet and, if needed, other blood pressure-lowering drugs.

Caduet reduced patients' calculated 10-year risk of total CHD, demonstrating a relative risk reduction of 27 percent after 12 months of treatment compared with usual care. Risk was assessed using a Framingham model, which calculates heart disease risk based on a combination of health and lifestyle factors, including sex, age, blood pressure, total or LDL-cholesterol, HDL cholesterol, smoking and diabetes status.

A secondary trial endpoint of calculated fatal CVD risk reduction showed a 23 percent relative difference between the two treatment arms, with a greater reduction in the Caduet arm, as measured with SCORE (Systematic Coronary Risk Evaluation), a European model. The risk factors included in the SCORE calculation are sex, age, smoking, systolic blood pressure, and total cholesterol.

In this trial, Caduet was generally well-tolerated. The adverse event profile in the Caduet arm was consistent with previous safety experience for this medication.

About CHD

An estimated 16.7 million deaths annually worldwide - or 29.2 percent of total deaths - result from various forms of CVD, which are often caused in part by high blood pressure and high cholesterol. These two risk factors frequently occur together; an estimated 55 percent of people with high blood pressure also have high cholesterol, and 43 percent of those with high cholesterol also have high blood pressure.

About the CRUCIAL Study

The CRUCIAL trial was designed to compare the impact on calculated Framingham risk for coronary heart disease of a Caduet-based treatment strategy of simultaneously lowering blood pressure and cholesterol with that of usual care. CRUCIAL was a 12-month, international, multicenter, prospective, cluster-randomized, parallel-design, open-label trial conducted in 19 countries in Asia, the Middle East, Europe, and Latin America.

For this study, cluster-randomization was used to prevent potential cross-over effects between treatment arms in this open-label study mimicking real-world clinical practice. In

general, in a cluster-randomized trial, doctors, not patients, are randomized to the relevant treatments; physicians then treat all their enrolled patients with their assigned therapy – in this case, either Caduet or usual care. To ensure similar patient types in both trial arms, doctors enrolled their eligible patients in the study before knowing which treatment they would be assigned.

Important Prescribing Information

Caduet is a prescription drug that combines two medicines, Norvasc® (amlodipine besylate) and Lipitor® (atorvastatin calcium). Norvasc is used to treat high blood pressure (hypertension), chest pain (angina), or blocked arteries of the heart (coronary artery disease); Lipitor is used along with a low-fat diet to lower the LDL (“bad”) cholesterol and triglycerides in the blood. It can raise the HDL (“good”) cholesterol as well. Lipitor is used to lower the risk of 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 also lower the risk of heart attack or stroke in patients with diabetes and risk factors such as diabetic eye or kidney problems, smoking, or high blood pressure.

Caduet 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.

If you take Caduet, tell your doctor if you feel any new muscle pain or weakness. This could be a sign of rare but serious muscle side effects. Tell your doctor about all of the medicines you take. This may help avoid serious drug interactions. Your doctor should do blood tests to check your liver function before and during treatment and may adjust your dose. If you have any heart problems, be sure to tell your doctor.

The most common side effects are edema, headache and dizziness.

Caduet is one of many options for treating high blood pressure and high cholesterol, in addition to diet and exercise.

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