



Results from Largest Statin Study of Patients with Alzheimer's Disease Show Lipitor(R) Has No Significant Impact on Disease

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Study Further Confirms Safety Profile of Lipitor 80 mg In Elderly Patients

(BUSINESS WIRE)--In a study in patients with mild-to-moderate Alzheimer's disease (AD), the addition of Lipitor (atorvastatin calcium tablets) 80 mg to Aricept® (donepezil HCl) 10 mg showed no significant differences in cognition or global function (key measures of Alzheimer's progression) compared to placebo plus Aricept 10 mg. Furthermore, no statistically significant differences were seen on various cognitive, behavioral and functional secondary endpoints. However, the Lipitor arm was not associated with greater cognitive decline than the placebo arm in this trial. The results were presented today at the annual American Academy of Neurology meeting in Chicago.

The 18-month study, called Lipitor's Effect on Alzheimer's Dementia (LEADe), included 640 patients and is the largest statin study in Alzheimer's disease.

While rates of decline in cognition and global function were similar for both the Lipitor and placebo groups, there were some interesting findings from the trial:

In a sub set of 64 patients for whom MRI scans were available, patients in the Lipitor arm had significantly less decline in hippocampal volume in the brain compared to the placebo arm. While the clinical significance of this result is not yet fully understood, less decline in hippocampal volume may be beneficial since declines have been associated with the progression of Alzheimer's disease. This finding requires further investigation and analysis.

In a sub-analysis completed after the trial, men in the Lipitor arm had a significantly slower rate of decline in cognition compared to men in the placebo arm. There was no difference in the rate of decline in cognition in women in the Lipitor arm compared to women in the placebo arm. However, no definitive conclusions can be drawn from this post-hoc analysis.

“The results of our investigation of Lipitor on the symptoms of Alzheimer’s disease have been long awaited,” said Professor Howard Feldman, chair of the LEADe Steering Committee and professor and head of the division of neurology, University of British Columbia Hospital in Canada. “While the LEADe study did not demonstrate significant benefits on the symptoms of mild to moderate Alzheimer’s disease, there are some noteworthy findings that require further analysis and should inform further research to determine the potential for statin use in this population.”

Lipitor 80 mg was shown to be well tolerated and the incidence of liver and muscle adverse events in patients was low.

Aricept was selected as the background therapy since it is proven effective for treating the symptoms of Alzheimer’s and is the most widely used cholinesterase inhibitor. The effect of Aricept on Alzheimer’s was not investigated in this study.

“Over the past 15 years, Pfizer has been committed to researching the potential benefit of Lipitor in patients at various levels of cardiovascular risk as well as in non cardiovascular diseases such as Alzheimer’s disease,” said Dr. Rochelle Chaiken, vice president of the cardiovascular/metabolic team in Pfizer global medical. “While we are not planning additional studies with Lipitor in patients with Alzheimer’s disease at this time, LEADe provides the medical community with important data. In addition, Pfizer is committed to advancing research and treatment in Alzheimer’s disease.”

About Alzheimer’s Disease

Alzheimer’s disease is a progressive degenerative brain disorder that gradually destroys a person’s memory and ability to learn, reason, make judgments, communicate, and carry out daily activities. As the disease progresses, patient may experience changes in personality and behavior, such as anxiety, suspiciousness or agitation, as well as delusions or hallucinations.

About Lipitor

Lipitor is the most prescribed cholesterol-lowering therapy in the world, with nearly 144 million patient-years of experience. Lipitor is supported by an extensive clinical trial program involving more than 400 ongoing and completed trials with more than 80,000 patients.

Important U.S. Prescribing Information for Lipitor

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.

About Aricept

Once-a-day prescription ARICEPT® (donepezil HCl tablets) is indicated for the treatment of dementia of the Alzheimer’s type. Efficacy has been demonstrated in patients with mild, moderate and severe Alzheimer’s disease (AD). ARICEPT helps with memory, thinking and everyday tasks.

ARICEPT is the number-one prescribed AD medication worldwide, with more than 3 billion patient days of ARICEPT therapy sold. Nearly 2.3 million people in the United States alone have begun ARICEPT therapy.

Important U.S. Prescribing Information for Aricept

ARICEPT is the first once-a-day Alzheimer's prescription medication available in the U.S. and can be taken with or without food. Available in 5 mg or 10 mg dosage strengths, ARICEPT 5 mg and 10 mg are approved for the treatment of mild to moderate AD. ARICEPT 10 mg (after four to six weeks at 5 mg) is approved for the treatment of severe AD. ARICEPT® ODT™ (donepezil HCl) Orally Disintegrating Tablets are available in the U.S. in 5 mg and 10 mg tablets, providing the same dosage strength of drug as ARICEPT tablets.

ARICEPT is well tolerated but may not be for everyone. People at risk for stomach ulcers or who take certain other medicines should tell their doctors because serious stomach problems, such as bleeding, may get worse. Some people who take ARICEPT may experience fainting. Some people may have nausea, vomiting, diarrhea, bruising, or not sleep well. Some people may have muscle cramps or loss of appetite or may feel tired. In studies, these were usually mild and temporary.

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

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