

[News Releases](#)[Fact Sheet](#)[Photos](#)[Press Kits](#)[Media Contact Info](#)

Schering-Plough News Release

Merck/Schering-Plough Pharmaceuticals Provides Results of the ENHANCE Trial

WHITEHOUSE STATION, N.J. & KENILWORTH, N.J.--(BUSINESS WIRE)--Nov. 19, 2007--

Merck/Schering-Plough Pharmaceuticals announced today the primary endpoint and other results of the ENHANCE (Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia) trial. Merck/Schering-Plough has submitted an abstract on the ENHANCE trial for presentation at the American College of Cardiology meeting, which will be held in March 2008, and is awaiting notification of acceptance from the College.

ENHANCE was a surrogate endpoint trial conducted in 720 patients with Heterozygous Familial Hypercholesterolemia (HeFH), a rare condition that affects approximately 0.2 percent of the population. All analyses were conducted in accordance with the original statistical analysis plan. The primary endpoint was the mean change in the intima-media thickness (IMT) measured at three sites in the carotid arteries (the right and left common carotid, internal carotid and carotid bulb) between patients treated with ezetimibe/simvastatin 10/80 mg versus patients treated with simvastatin 80 mg alone over a two year period.

There was no statistically significant difference between treatment groups on the primary endpoint. The change from baseline in the mean carotid IMT was 0.0111 mm for the ezetimibe/simvastatin 10/80 mg group versus 0.0058 mm for the simvastatin 80 mg group ($p = 0.29$). At baseline, the mean carotid IMT measurement for ezetimibe/simvastatin was 0.68 mm and for simvastatin 80 mg was 0.69 mm. There was also no statistically significant difference between the treatment groups for each of the components of the primary endpoint, including the common carotid artery. Key secondary imaging endpoints showed no statistical difference between treatment groups.

The overall incidence rates of treatment-related adverse events, serious adverse events or adverse events leading to discontinuation were generally similar between treatment groups. The incidence of consecutive elevations of serum transaminases (greater than or equal to 3x ULN) was 10 out of 356 for ezetimibe/simvastatin (2.8 percent) as compared to 8 out of 360 for simvastatin (2.2 percent). Incidence of elevated creatine phosphokinase (greater than or equal to 10xULN) was 4 out of 356 (1.1 percent) in the ezetimibe/simvastatin group and 8 out of 360 (2.2 percent) in the simvastatin group and two cases (0.6 percent) of CPK greater than or equal to 10xULN associated with muscle symptoms in the ezetimibe/simvastatin group and one case (0.3 percent) in the simvastatin group. There were no cases of rhabdomyolysis. Both medicines were generally well tolerated.

Overall, the safety profiles of ezetimibe/simvastatin and simvastatin alone were similar and