Merck says cholesterol drug failed to show benefit

20 December 2012

Drugmaker Merck & Co. said it will not seek U.S. approval for its cholesterol drug Tredaptive and is recommending doctors abroad stop prescribing it to new patients, based on failed study results.

The drug is sold in about 40 countries in Europe and elsewhere but is not a major product for Merck. In the first three quarters of 2012 the drug posted $13 million in sales.

The company said Thursday that results from a 25,700-patient study showed that adding Tredaptive to traditional statin therapy did not lower the risk of heart attack, stroke and related problems. Patients taking the cholesterol combination pill were also more likely to suffer serious, non-fatal adverse events. The study compared 4-year outcomes for patients taking Tredaptive plus statin drugs, to those taking statins alone.

Statins are a class of drugs that have long been used to lower levels of LDL, or "bad," cholesterol and slightly raise levels of HDL, or "good," cholesterol in the blood.

Tredaptive is a combination pill made up of niacin, which boosts good cholesterol, and laropiprant, which reduces the facial flushing caused by niacin.

Cowen & Co. analyst Steve Scala noted that the current statin treatment is a "high bar for a trial to overcome due to the substantial risk reduction associated with these drugs." Scala said in a research note that the uncertainty around the Tredaptive results "had been a long-standing reason to avoid Merck shares."

The Food and Drug Administration rejected Tredaptive in 2008 pending the more information about the drug's effects on the heart.

Company shares fell $1.03, or 2.4 percent, to $42.63 in morning trading.