REVEAL: CETP Inhibitor Anacetrapib Meets Primary End Point

Megan Brooks

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KENILWORTH, NJ — Top-line results from the Randomized Evaluation of the Effects of Anacetrapib Through Lipid Modification (REVEAL) outcomes study of anacetrapib show the drug met its primary end point, Merck announced today[1].

The investigational cholesteryl ester transfer protein (CETP) inhibitor significantly reduced major coronary events, defined as the composite of coronary death, MI, and coronary revascularization, compared with placebo in patients at risk for cardiac events already receiving a statin drug, the company said in a news release.

The safety profile of anacetrapib was "generally consistent" with that demonstrated in previous studies of the drug, including accumulation of anacetrapib in adipose tissue, as has been previously reported, the company said.

The REVEAL study is a randomized, double-blind placebo-controlled phase 3 clinical trial assessing the efficacy and safety of adding anacetrapib (100 mg daily) to effective LDL-lowering treatment with atorvastatin for a median duration of at least 4 years among about 30,000 patients aged 50 and older at high risk of cardiovascular events.

Results of the REVEAL study will be presented at the European Society of Cardiology (ESC) 2017 Congress at the end of August in Barcelona, Spain, the company said.

Merck said it will review the results of the trial with external experts and consider whether to file a new drug application with the US Food and Drug Administration (FDA) and other regulatory agencies.

CETP inhibitors are a closely watched class of agents with potent LDL-lowering ability but a disappointing development history.

In 2006, the first drug in the class to reach advanced clinical testing, Pfizer's torcetrapib, was pulled out of the pipeline after a large trial showed an increased risk of death and cardiovascular events.

In 2012, another CETP inhibitor, dalcetrapib (Hoffman-La Roche, Ltd) failed after an interim analysis of a major outcomes trial showed no benefit.

In 2015, Eli Lilly halted development of evacetrapib due to "insufficient efficacy."

The Merck release notes that "REVEAL was designed and independently conducted by investigators at the Clinical Trial Service Unit (CTSU) at the University of Oxford, the trial's regulatory sponsor, in collaboration with the TIMI Study Group based at Brigham and Women's Hospital in Boston and Merck. Merck provided funding for REVEAL."

References

1. Merck. Merck provides update on REVEAL outcomes study of anacetrapib [press release]. June 27, 2017. Available here.