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IN BRIEF

Ezetimibe/Simvastatin (Vytorin) in Chronic Kidney Disease

An FDA advisory committee has voted in favor of approving ezetimibe/simvastatin (Vytorin – Merck) for prevention of major cardiovascular events in patients with chronic kidney disease who are not on dialysis. The FDA itself is expected to make a decision on this potential new indication in the first quarter of 2012.

The manufacturer’s application for this new indication was based on a double-blind, randomized trial (SHARP) that compared the combination of ezetimibe 10 mg and simvastatin 20 mg with placebo in 9270 patients with chronic kidney disease who did not have a history of myocardial infarction or coronary revascularization. About one-third of patients were already on hemodialysis at the start of the trial. Over a median of 4.9 years, a major atherosclerotic event (the primary endpoint) occurred in 526 patients (11.3%) taking the active drugs and in 619 (13.4%) taking placebo. Myopathy occurred in 9 patients (0.2%) randomized to ezetimibe/simvastatin and in 5 (0.1%) of those in the placebo group, not a significant difference.

Whether simvastatin alone, which would cost much less, would similarly improve outcomes in such patients remains to be determined. The FDA advisory committee did not recommend approval of Vytorin for patients who were on hemodialysis. Previous trials with a statin alone in patients with end-stage renal disease on hemodialysis failed to show significant benefits in clinical outcomes.


