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On Drugs and Therapeutics

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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.[1] 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.[2] Previous trials with a statin alone in patients with end-stage renal disease on hemodialysis failed to show significant benefits in clinical outcomes.[3,4]

1. C Baigent et al. The effects of lowering LDL cholesterol with simvastatin plus ezetimibe in patients with chronic kidney disease (Study of Heart and Renal Protection): a randomised placebo-controlled trial. Lancet 2011; 377: 2181.
2. S Sutter. Merck's bid for Vytorin CV benefit claim muddled by earlier statin failures in dialysis patients. The Pink Sheet, November 7, 2011.
3. C Wanner et al. Atorvastatin in patients with type 2 diabetes mellitus undergoing hemodialysis. N Engl J Med 2005; 353:238.
4. BC Fellström et al. Rosuvastatin and cardiovascular events in patients undergoing hemodialysis. N Engl J Med 2009; 360:1395.

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The Medical Letter, Inc.
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