

Industry Spotlight

Vytorin for CKD?

Around press time, news appeared that a drug once used to lower cholesterol was showing promise for patients with chronic kidney disease (CKD).

The drug, called Vytorin – a combination of cholesterol-lowering drugs simvastatin and ezetimibe, ran into trouble when it was discovered in trials that the drug wasn't more effective than simvastatin alone, National Public Radio reported online. Then reports surfaced through a study that suggested Vytorin raised the risk of cancer slightly, but a U.S. Food and Drug Administration analysis failed to find any increase in cancer in a new study, according to NPR.

Now a new study submitted to the FDA by Vytorin maker Merck from the SHARP (Study of Heart and Renal Protection) is presenting data that says the agency should approve a new use for the drug (<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM277652.pdf>) The data showed enough merit to warrant a discussion at the Nov. 2 meeting of the FDA Endocrinologic and Metabolic Drugs Advisory Committee.

This new study's data has provided the basis for Merck to receive a hearing, because Vytorin shows indications that it reduces the risk of major cardiovascular events in CKD. In particular, Vytorin, compared with placebo, significantly lowered the risk of coronary revascularization, and major atherosclerotic events, as well as the risk of ischemic stroke.

The FDA researchers who reviewed the SHARP data say that Vytorin "cut kidney disease patients' heart-related problems by 16 percent compared with placebo," CBS/AP reported. Results were different when patients were on dialysis. Dialysis patients only had a 6 percent drop in heart problems, compared with a 22 percent drop for CKD patients who weren't on dialysis.

The FDA reviewers also addressed the cancer question in their report to the advisory panel: "Risk of cancer did not increase consistently over time with longer use of ezetimibe/simvastatin, as would be expected if a drug caused cancer or promoted the growth of pre-existing cancers," they wrote.

Chronic kidney disease, which affects about 14 percent of the U.S. population, raises the risk of developing heart disease or having a stroke, Reuters noted. Patents on Vytorin and Zetia (the ezetimibe part of Vytorin) both expire in 2017. ●

Turnabout Is Fair Play

DaVita, the second largest provider of dialysis services in North America, is acquiring its first operations in Europe—in Germany.

What makes the deal particularly interesting is that Germany is the headquarters of the largest provider of dialysis services and products worldwide. Fresenius Medical Care

is based in Bad Homburg, Germany. Fresenius North America is well established, but DaVita is just starting to get its feet wet across the oceans.

DaVita already has expanded into Asia, providing dialysis services in Singapore and in Bangalore, India, and has an agreement to develop and operate dialysis clinics in Malaysia, according to the company web site.

"The time is right for DaVita to extend to Europe and Asia," said DaVita chairman and CEO Kent Thiry.

"Our patient-centric care model is being well received on both continents."

Denver-based DaVita is taking it slowly. The *Denver Post* reports that Thiry is cautiously optimistic—and candid—about the new expansion plans. "If I was smarter, we would have started this several years ago," Thiry said. "Over the next 10 years, we intend to deliberately and thoroughly create a material global presence. ... We'll make some mistakes, since we're new at it." ●

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