

Alirocumab cuts apheresis rates in familial hypercholesterolemia

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Patients who have heterozygous familial hypercholesterolemia (HeFH), a condition that causes abnormally raised low-density lipoprotein cholesterol (LDL-C) levels and premature cardiovascular disease, can significantly reduce or even eliminate their need for expensive and time-consuming apheresis treatments with the PCSK9 inhibitor alirocumab.

Results of the phase 3 ODYSSEY-ESCAPE trial, reported in a Hot Line session at ESC Congress 2016, "suggest a role for alirocumab in the overall management of <u>patients</u> with HeFH undergoing regular lipoprotein apheresis therapy, with the potential to avoid apheresis treatments or delay the requirement for such treatments," said the study's lead investigator Patrick M. Moriarty, MD, from the University of Kansas Medical Center, in Kansas City, KS, USA.

The findings, published simultaneously in the *European Heart Journal*, have exciting implications for HeFH patients, many of whom struggle with weekly apheresis treatments, he explained.

"Being able to reduce or eliminate apheresis would be a major breakthrough for these patients who spend \$50,000 to \$75,000 a year, and 3-4 hours every 1-2 weeks to clear their blood of excess LDL-C. If our results are confirmed in other studies this could mark a new era for patients with familial hypercholesterolemia who have uncontrolled cholesterol levels and resistance to normal medical management."

The study included 62 HeFH patients from 14 centers in the US and



Germany, who were undergoing apheresis either weekly or every 2 weeks.

They were randomized to receive subcutaneous injections of either alirocumab 150 mg (n=41) or placebo (n=21) every 2 weeks for 18 weeks while still continuing their regular lipid-lowering medications (LLT).

Apheresis treatments during the study were scheduled over 2 phases:

Until week 6, the rate was fixed according to the patient's established schedule, but was then adjusted between weeks 7 through 18 based on individual needs. If a patient's LDL-C had dropped by 30% or more since the start of the study, apheresis was skipped.

At the end of the study, the alirocumab-treated patients had a 75% greater reduction in apheresis compared to those on placebo. (P

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