Alirocumab shows promise as treatment to reduce LDL-cholesterol in Phase III study

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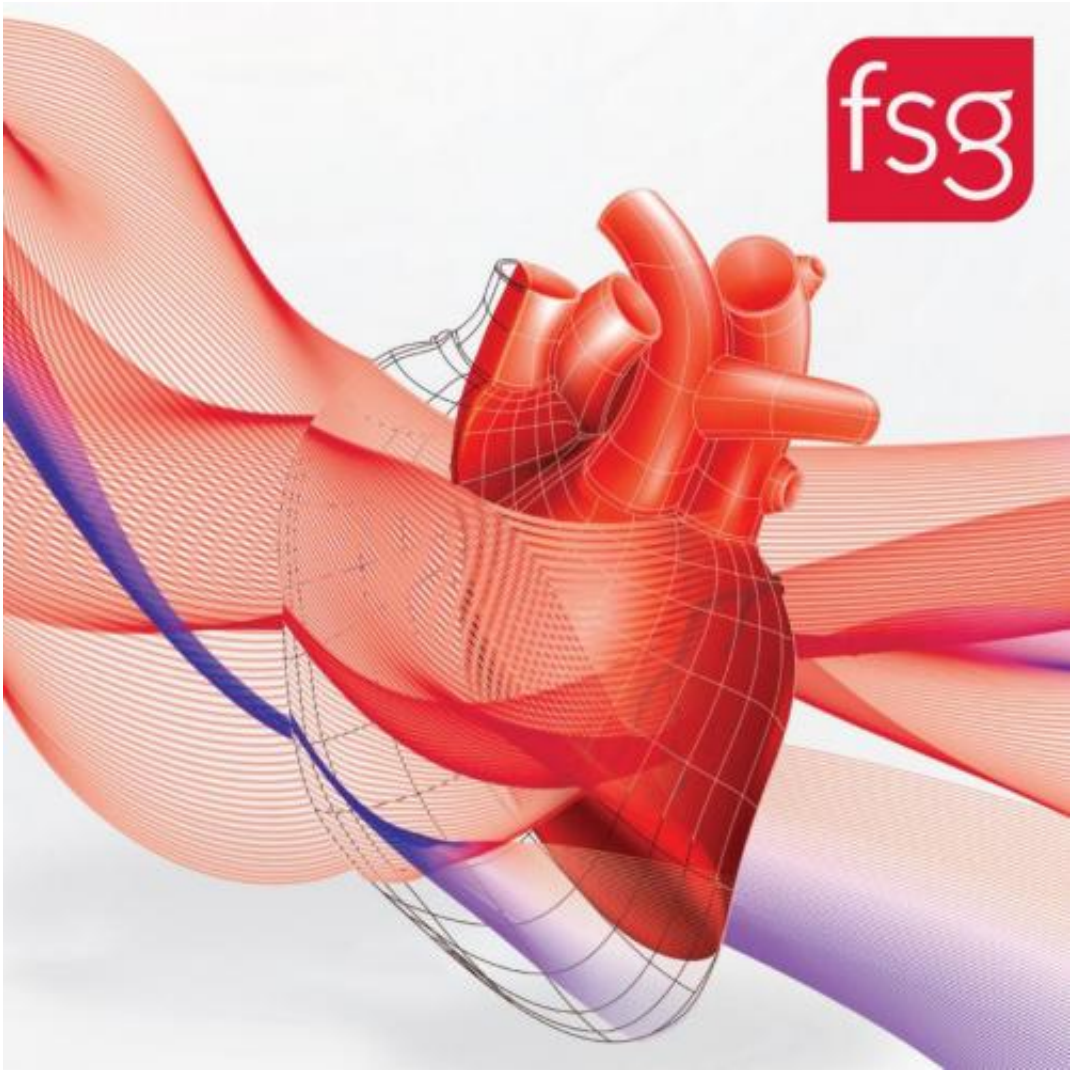

Credit: Future Science Group

A recently published clinical trial report reviewing the first completed Phase III study in the ODYSSEY development program has shown that alirocumab showed significantly better LDL-C lowering than ezetimibe, with a comparable safety profile to ezetimibe.

The report, which is published in the January issue of *Future Cardiology*, provides a comprehensive overview of the ODYSSEY MONO trial, including detail on the study design, data analysis, results and discussion on the implications of the findings, authored by lead investigator of the trial Eli M Roth.

LDL-cholesterol (LDL-C) is considered to be a major modifiable risk factor for the development of atherosclerosis and cardiovascular disease (CVD), the leading cause of death worldwide. LDL-C is identified as the primary target of cholesterol-lowering therapy in both North American and European guidelines. Statins are the recommended first-line therapy for lowering LDL-C.

Alirocumab (formerly SAR236553/REGN727) is a fully human mAb to PCSK9 - the first in this class of drugs to complete a Phase III trial, and reported to have a significant role in the regulation of LDL-C - being developed jointly by Sanofi (France) and Regeneron (NY, USA).

This first completed Phase III study, entitled ODYSSEY MONO, tested the new lower 75-mg dose of alirocumab subcutaneously every 2 weeks as a monotherapy versus ezetimibe 10 mg per os every day as a control. Inclusion criteria included patients with an LDL-C between 100 mg/dl (?2.6 mmol/l) and 190 mg/dl (