Long-term evolocumab therapy leads to further reductions in cardiovascular events

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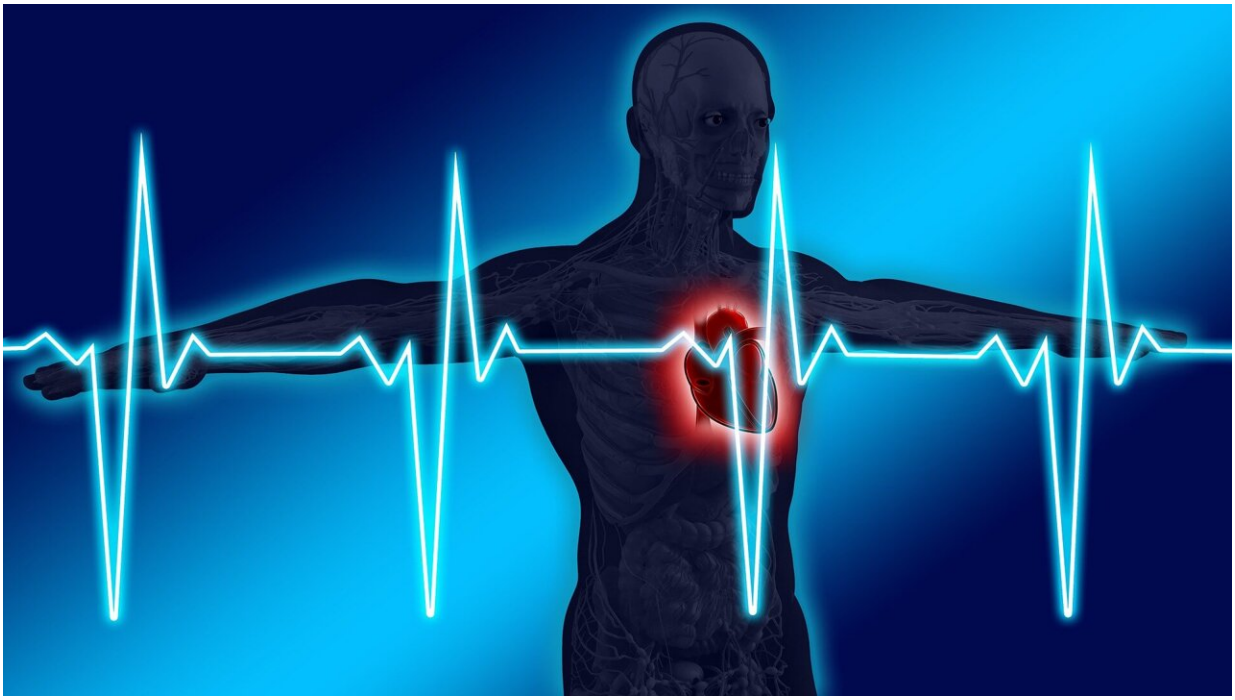

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Long-term low-density lipoprotein (LDL) cholesterol lowering with evolocumab is safe and well tolerated and leads to further reductions in cardiovascular events compared with shorter treatment, according to late breaking results from the FOURIER open-label extension (OLE) study presented in a Hot Line session on 29 August at ESC Congress 2022.

Principal investigator Dr. Michelle O'Donoghue of Brigham and Women's Hospital, Boston, US said, "PCSK9 inhibitors lead to marked reductions in LDL cholesterol. The major trials to date have only had median treatment durations of two to three years. However, in clinical practice lipid-lowering therapy is typically administered chronically. FOURIER-OLE was therefore conducted to better understand the long-term safety, tolerability, lipid levels, and risk of major adverse cardiovascular events in patients getting prolonged treatment with the PCSK9 inhibitor evolocumab."

In FOURIER, evolocumab reduced the risk of cardiovascular events and was safe and well-tolerated over a median follow up of 2.2 years. FOURIER-OLE was conducted at select sites in Europe and the US that participated in FOURIER. The study enrolled 6,635 patients (3,355 randomized to evolocumab and 3,280 to placebo in FOURIER) who completed FOURIER. All patients in the extension study self-injected evolocumab with the choice of 140 mg every two weeks or 420 mg monthly.

Study visits were at week 12 and then every 24 weeks and included clinical assessments and fasting lipids. The primary objective was to report the long-term safety and tolerability of the drug. Major adverse cardiovascular events were reviewed by an independent clinical events committee.

The median follow-up in the extension study was 5.0 years. The maximum exposure to evolocumab in FOURIER plus FOURIER-OLE was 8.4 years. At 12 weeks in FOURIER-OLE, the median LDL cholesterol was 30 mg/dl and 63.2% of participants achieved LDL cholesterol

Citation: Long-term evolocumab therapy leads to further reductions in cardiovascular events