Background

Efficacy and Safety of Alirocumab versus Ezetimibe over 104 Weeks in Patients with Hypercholesterolemia and High Cardiovascular Risk: Final Results from ODYSSEY COMBO II

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Objectives

The aim of the study was to evaluate the efficacy and safety of alirocumab in the COMBO II study up to the end of the study (104 weeks) in order to evaluate the long-term effects of alirocumab, as well as post hoc analysis of patients with hypercholesterolemia and established coronary heart disease (CHD) or CHD risk equivalents who received alirocumab in the COMBO II trial.

Methods

The study included patients with hypercholesterolemia and established coronary heart disease who required additional LDL-C reduction despite receiving maximally tolerated lipid-lowering therapy. Two patients randomized in the alirocumab group had no fully documented CHD or CHD risk equivalents. The study included patients with hypercholesterolemia and established coronary heart disease who required additional LDL-C reduction despite receiving maximally tolerated lipid-lowering therapy. Two patients randomized in the alirocumab group had no fully documented CHD or CHD risk equivalents.

Screening

The study included patients with hypercholesterolemia and established coronary heart disease who required additional LDL-C reduction despite receiving maximally tolerated lipid-lowering therapy. Two patients randomized in the alirocumab group had no fully documented CHD or CHD risk equivalents.

Results

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Alirocumab is a fully human monoclonal antibody directed against proprotein convertase subtilisin-kexin type 9 (PCSK9), which is responsible for rapid degradation of the LDL receptor. Alirocumab treatment reduces LDL-C levels by up to 50% and may also reduce levels of other cardiovascular risk factors.

Efficacy

The primary endpoint was percent change in calculated LDL-C from baseline to Week 24, using all on-treatment data. The study also analyzed by mixed-effect model with repeat measurement using on-treatment data.

Safety

Adverse events (AEs) related to diabetes mellitus or diabetic complications were evaluated at Weeks 0, 12, 24, 52, and 104. The presence of anti-drug antibodies (ADAs) was evaluated at Weeks 0, 12, 24, 52, and 104.

Conclusion

Three dose levels indicate that efficacy and safety of alirocumab are maintained throughout 2 years of treatment in patients with hypercholesterolemia and established coronary heart disease. The ongoing ODYSSEY COMBO II study will continue approximately 15,000 patients to confirm the long-term safety and efficacy of alirocumab

References


