Patients were eligible to enter OLE if they had a diagnosis of HeFH and had completed the parent studies.

Patients entered OLE and received alirocumab 75 mg (FH I, FH II and LONG TERM patients) or 150 mg (HIGH FH patients) Q2W regardless of the treatment regimen received at completion of the parent study (Figure 1).

The alirocumab starting dose of 75 mg Q2W for patients from FH I, FH II, and LONG TERM studies was chosen because for patients in whom a significant reduction of LDL-C was achieved with alirocumab 150 mg in double-blind treatment, it may not have been achieved to reach their pre-defined LDL-C goals. However, patients from HIGH FH had high baseline LDL-C (>160 mg/dL). So the higher starting dose of alirocumab 150 mg Q2W was considered more appropriate.

The end of the parent period corresponded with Day 1 of OLE (8-week wash-out period off-treatment prior to OLE, during which patients did not receive alirocumab).

From Week 12, dosing adjustment was considered per investigator’s clinical judgment and each patient’s LDL-C level.

Throughout the treatment period, patients received, as far as possible, the same stable maximally tolerated statin dose with or without other lipid-lowering therapies as during the parent study.

- At the time of analysis, 938 patients (95.2%) had completed OLE baseline LDL-C values reflect the 8-week wash-out long-term and placebo allocation in the other parent studies (the wash-out) Table 2.

- Other lipid levels of OLE entry were generally higher in patients who received placebo in the parent studies compared with patients who received alirocumab (Table 2).

- In the OLE, the mean LDL-C levels were 76.7 mg/dL, a mean reduction of 46.7% compared with baseline levels of the parent studies (Figure 2).

- Reduction in LDL-C levels was maintained throughout the study (up to Week 72; mod ITT population).

- At the time of analysis, reductions in LDL-C levels was maintained throughout the study (up to Week 72; mITT population). Data from 310 patients with diabetes (safety population) in OLE, LDL-C, low-density lipoprotein cholesterol; mITT, modified intent-to-treat; OLE, open-label extension; SE, standard error.

- The safety profile was comparable between patients treated with alirocumab or placebo in the parent studies.

- Overall safety profile was comparable between patients treated with alirocumab or placebo in the parent studies Table 3.

- The rates of TEAEs of special interest are presented in Table 4.

CONCLUSIONS

In this OLE study of patients with HeFH, alirocumab demonstrated a durable and robust treatment effect, yielding a 47% reduction in LDL-C at Week 48 compared with baseline levels.

During ODYSSEY OLE (at least 12 months of open-label treatment following 18 months of double-blind treatment), alirocumab was generally well-tolerated in patients with HeFH.

The safety profile observed in this real-world setting is consistent with previous real-world studies.

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