Praluent® (alirocumab) – ODYSSEY Outcomes study results

- On March 10, 2018, Regeneron and Sanofi announced that a clinical study demonstrated that Praluent (alirocumab) significantly reduced the risk of major adverse cardiovascular events (MACE) in patients who had suffered a recent acute coronary syndrome (ACS) event.
    - The ODYSSEY Outcomes study results were recently presented at the American College of Cardiology's 67th Scientific Session.
- Praluent is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of low-density lipoprotein cholesterol (LDL-C).
- ODYSSEY Outcomes was a randomized, placebo-controlled clinical study of 18,924 patients who had experienced an ACS between 1 – 12 months (median 2.6 months) before enrolling in the trial and were receiving maximally-tolerated statins. Approximately 90% of patients in both groups were on a high-intensity statin. The trial was designed to maintain the patients' LDL-C levels between 25 – 50 mg/dL, using two different doses of Praluent (75 mg and 150 mg).
    - Compared to placebo, Praluent reduced the overall risk of the primary efficacy outcome, MACE, defined as the time to first occurrence of death from coronary heart disease (CHD), non-fatal myocardial infarction (MI), fatal or non-fatal ischemic stroke, or unstable angina requiring hospitalization (Praluent: 9.5% vs. placebo: 11.1%; HR = 0.85 [95% CI: 0.78 – 0.93], p = 0.0003).
    - Praluent was associated with a lower risk of non-fatal MI (Praluent: 6.6% vs. placebo: 7.6%; HR = 0.86 [95% CI: 0.77 – 0.96], p = 0.006), ischemic stroke (Praluent: 1.2% vs. placebo: 1.6%; HR = 0.73 [95% CI: 0.57 – 0.93], p = 0.01), and unstable angina (Praluent: 0.4% vs. placebo: 0.6%; HR = 0.61 [95% CI: 0.41 – 0.92], p = 0.02).
    - Praluent was associated with a lower risk of all-cause mortality (Praluent: 3.5% vs. placebo: 4.1%; HR = 0.85 [95 % CI: 0.73 – 0.98], nominal p = 0.026), and there were also numerically fewer CHD deaths (Praluent: 2.2% vs. placebo: 2.3%; HR = 0.92 [95% CI: 0.76 – 1.11], p = 0.38).
- Patients with baseline LDL-C levels ≥ 100 mg/dL experienced a more pronounced effect from Praluent, reducing their risk of MACE by 24% (Praluent: 11.5% vs. placebo: 14.9%; HR = 0.76 [95% CI: 0.65 – 0.87]). In a post-hoc analysis of this group, Praluent was associated with a lower risk of death from any cause by 29% (Praluent: 4.1% vs. placebo: 5.7%; HR = 0.71 [95% CI: 0.56 – 0.90]).
- There were no new safety signals in the trial, with injection site reactions experienced more commonly in the Praluent group compared to patients on maximally-tolerated statins alone (Praluent: 3.8% vs. placebo: 2.1%). There was no difference in neurocognitive events (Praluent: 1.5% vs. placebo: 1.8%) or new-onset diabetes (Praluent: 9.6% vs. placebo: 10.1%).
- Based on the results of the ODYSSEY Outcomes trial, the Institute for Clinical and Economic Review (ICER) has calculated two updated value-based price benchmarks, net of rebates and discounts, for Praluent in patients with a recent acute coronary event: $2,300 – $3,400 per year if used to treat all patients who meet trial eligibility criteria, and $4,500 – $8,000 per year if used to treat higher-risk patients with LDL-C ≥ 100 mg/dL despite intensive statin therapy.

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- Based on the ICER assessment, Regeneron and Sanofi plan to offer health plans and payers net pricing adjustments if straightforward access is provided to high-risk patients. Regeneron and Sanofi also plan to work with cardiology healthcare professionals to define best practices in reducing barriers to access.