About ODYSSEY OUTCOMES

ODYSSEY OUTCOMES (n=18,924) assessed the effect of Praluent on the occurrence of major adverse cardiovascular events (MACE) in patients who had experienced an acute coronary syndrome (ACS) between 1-12 months (median 2.6 months) before enrolling in the trial, and who were already on intensive or maximally-tolerated statin treatment. Patients were randomized to receive Praluent (n=9,462) or placebo (n=9,462) and were assessed for a median of 2.8 years, with some patients being treated for up to five years. Approximately 90% of patients were on a high-intensity statin.

MACE, the primary endpoint, was a composite of death from coronary heart disease, nonfatal myocardial infarction, fatal or nonfatal ischemic stroke, or unstable angina requiring hospitalization.

The trial was designed to maintain patients' LDL-C levels between 25-50 mg/dL, using two different doses of Praluent (75 mg and 150 mg). Praluent-treated patients started the trial on 75 mg every 2 weeks and switched to 150 mg every 2 weeks if their LDL-C levels remained above 50 mg/dL (n=2,615). Some patients who switched to 150 mg switched back to 75 mg if their LDL-C fell below 25 mg/dL (n=805), and patients who experienced two consecutive LDL-C measurements below 15 mg/dL while on the 75 mg dose (n=730) stopped active Praluent therapy for the remainder of the trial.

About Praluent

Praluent inhibits the binding of PCSK9 (proprotein convertase subtilisin/kexin type 9) to the LDL receptor and thereby increases the number of available LDL receptors on the surface of liver cells to clear LDL, which lowers LDL-C levels in the blood. Praluent is being developed by Regeneron and Sanofi under a global collaboration agreement.

Praluent is approved in more than 60 countries worldwide, including the U.S., Japan, Canada, Switzerland, Mexico and Brazil, as well as the European Union (EU). In the U.S., Praluent is approved for use as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of LDL-C. The effect of Praluent on cardiovascular morbidity and mortality has not been determined.