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Under the Prescription Drug User Fee Act (PDUFA), the goal for a priority review is six months, for a target action date of July 24, 2015.

Alirocumab is an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9) that is intended for the treatment of patients with hypercholesterolemia.

The BLA for Praluent contains data from more than 5,000 patients, including 10 Phase 3 Odyssey trials.

Together with additional ongoing studies including Odyssey Outcomes, the Odyssey clinical trial program will include more than 23,500 patients at more than 2,000 study centers in double-blind, randomized, placebo-and active-controlled trials ranging from 24 weeks to approximately 5 years.

Earlier this month, the companies announced that the European Medicines Agency (EMA) accepted for review the marketing authorization application for Praluent in the European Union.

The EMA and FDA have conditionally accepted Praluent as the trade name for alirocumab.

The safety and efficacy of alirocumab have not been fully evaluated by any regulatory authority.