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EMA accepts marketing authorization application review for Praluent

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

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

Together, with additional ongoing studies including odyssey outcomes 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.

A biologics license application (BLA) for Praluent was submitted to the USFDA in the fourth quarter of 2014.

The EMA and USFDA 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.