

Enlicitide Decanoate MK-0616

Oral PCSK9 Inhibitor

Phase 3 Clinical Trials Program

Merck has a legacy and commitment to advancing research for people with cardiovascular diseases. This has inspired our ongoing efforts to bring forward potential new treatment options focused on helping to address the unmet needs of patients by pushing our science to new heights.

CORALreef Phase 3 Clinical Trials Summary

The CORALreef program is a set of Phase 3 clinical trials designed to evaluate the efficacy and safety of enlicitide decanoate (MK-0616)—an investigational oral PCSK9 inhibitor*—in adults who have high LDL-cholesterol (commonly known as “bad cholesterol”) and increased risk for atherosclerotic cardiovascular disease (ASCVD) events despite taking therapies like statins to treat their condition. The program aims to evaluate the efficacy of enlicitide in lowering LDL-C levels and risk of ASCVD events, as well as its safety and tolerability.

Development Program	Study Number & Link
A Study of Enlicitide Decanoate (Oral PCSK9 Inhibitor) in Adults With Heterozygous Familial Hypercholesterolemia	CORALreef HeFH (heterozygous familial hypercholesterolemia) - NCT05952869
A Study to Evaluate the Efficacy and Safety of Enlicitide Decanoate (Oral PCSK9 Inhibitor) Compared With Ezetimibe or Bempedoic Acid or Ezetimibe and Bempedoic Acid in Adults With Hypercholesterolemia	CORALreef AddOn - NCT06450366
A Study of Enlicitide Decanoate (Oral PCSK9 Inhibitor) in Adults With Hypercholesterolemia	CORALreef Lipids - NCT05952856
Enlicitide Decanoate (Oral PCSK9 Inhibitor) Cardiovascular Outcomes Study	CORALreef Outcomes - NCT06008756

In addition, the CORALreef Extension study ([NCT06492291](#)) is a rollover study for participants who were enrolled in earlier enlicitide clinical trials and wished to continue to receive enlicitide as part of a clinical trial.

*Proprotein convertase subtilisin/kexin type 9.

†Low-density lipoprotein cholesterol

‡Patients enrolled in these studies will continue to receive statins, dosed at a high or moderate intensity. CORALreef Lipids also allows patients who are on low-intensity or no statins, but only if they had documented intolerance to statins in the past.