

A Study of Enlicitide Decanoate (MK-0616, an Oral PCSK9 Inhibitor) in Children and Adolescents With Heterozygous Familial Hypercholesterolemia (MK-0616-029)

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 6 years to 17 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

Inclusion criteria include, but are not limited to:

- Has possible or definite diagnosis of HeFH based on a locally accepted diagnostic algorithm or diagnosis by genetic testing results
- Has a fasted LDL-C value (evaluated by the central laboratory) that is ≥ 130 mg/dL
- Is receiving either:
 - An optimized daily dose of statin ($\pm$ nonstatin LLT)
 - A nonstatin LLT with documented intolerance to at least 2 different statins, or documented intolerance to 1 statin plus refusal of statin therapy by the participant or legally acceptable representative
- Is on a stable dose of all background LLTs for at least 30 days prior to screening, with no medication or dose changes planned during participation in Part A or Part B

Exclusion Criteria:

Exclusion criteria include, but are not limited to:

- Has a history of homozygous FH based on genetic or clinical criteria, or history of known compound heterozygous FH, or double heterozygous FH
- Has a history of nephrotic syndrome
- Has any clinically significant malabsorption condition based on investigator assessment
- Was previously treated/is being treated with certain other cholesterol lowering medications, including proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors without adequate washout

Conditions & Interventions

Interventions:

DRUG: Enlicitide Decanoate, DRUG: Placebo

Conditions:

Heterozygous Familial Hypercholesterolemia (HeFH)

More Information

Description:

This study is designed to learn if enlicitide decanoate is safe and effective to treat children and adolescents with heterozygous familial hypercholesterolemia (HeFH) and high amounts of low-density lipoprotein cholesterol (LDL-C) in the blood. The goals of this study are to learn about the safety of enlicitide and if children tolerate it, what happens to enlicitide in a child's body over time, and if enlicitide works to lower cholesterol levels in children more than a placebo.

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Principal Investigator:

Principal Investigator ID:

Phase: PHASE2

IRB Number:

System ID: NCT07058077

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