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

NCT07058077

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Merck Sharp & Dohme LLC
Enrollment	153 participants

Key Eligibility Criteria

Inclusion (4)

- 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 e130 mg/dL
- Is receiving either an optimized daily dose of statin (± nonstatin LLT); or a nonstatin LLT with documented intolerance to at least 2 different statins or 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 (4)

- 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 principal 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

Locations (21 total)

Nemours/Alfred I. duPont Hospital for Children (Site 0001), Wilmington, Delaware, United States
Children's National Medical Center (Site 0015), Washington D.C., District of Columbia, United States
Excel Medical Clinical Trials (Site 0008), Boca Raton, Florida, United States
... and 18 more locations