Long-term Safety and Tolerability of Inclisiran in Participants With HeFH or HoFH Who Have Completed the Adolescent ORION-16 or ORION-13 Studies

Last Update: Mar 19, 2025
An Open-label, Single Arm, Multicenter Extension Study to Evaluate Long-term Safety and Tolerability of Inclisiran in Participants With Heterozygous or Homozygous Familial Hypercholesterolemia Who Have Completed the Adolescent ORION-16 or ORION-13 Studies (VICTORION-PEDS-OLE)
ClinicalTrials.gov Identifier:
NCT05682378
Novartis Reference Number:CKJX839C12001B
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this open-label, single arm, multicenter extension study is to evaluate the long-term safety and tolerability of inclisiran in participants with HeFH or HoFH who have completed the ORION-16 or ORION-13 studies. This is an open-label, single arm, multicenter study designed to evaluate long-term safety and tolerability of inclisiran. In addition, the study will provide participants the opportunity to have continued access to treatment with inclisiran.

Condition
Heterozygous or Homozygous Familial Hypercholesterolemia
Phase
Phase3
Overall Status
Recruiting
Number of Participants
154
Start Date
Feb 10, 2023
Completion Date
Mar 02, 2028
Gender
All
Age(s)
12 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Drug

Inclisiran

Inclisiran sodium 300mg (equivalent to 284mg inclisiran*) in 1.5mL solution administered subcutaneously in pre-filled syringe

Eligibility Criteria

Key inclusion:

* Male and female participants with a diagnosis of HeFH or HoFH who completed the ORION-16 or ORION-13 studies
* Per investigator's clinical judgment, participant derived benefit from treatment with inclisiran in the ORION-16 or ORION-13 studies

Key exclusion:

* Participants who in the feeder inclisiran ORION-16 and ORION-13 studies either screen failed or permanently discontinued from the treatment/study for any reason or had serious safety or tolerability issues related to inclisiran treatment
* Any uncontrolled or serious disease, or any medical, physical, or surgical condition, that may either interfere with participation in the clinical study or interpretation of clinical study results, and/or put the participant at significant risk

Brazil

Novartis Investigative Site

Recruiting

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Sao Paulo,SP,04023-900,Brazil

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Recruiting

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Recruiting

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Recruiting

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Israel

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Recruiting

Ramat Gan,52621,Israel

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Recruiting

Jerusalem,9112001,Israel

Jordan

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Recruiting

Irbid,22110,Jordan

Lebanon

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Recruiting

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