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

05/07/2025 06:49:02 **Main Information** Primary registry identifying number Protocol number LBCTR2023045322 CKJX839C12001B MOH registration number Study registered at the country of origin Study registered at the country of origin: Specify Yes Type of registration Type of registration: Justify Prospective N/A Date of registration in national regulatory agency **Primary sponsor** Primary sponsor: Country of origin Novartis Pharma AG Novartis Pharma AG Date of registration in primary registry Date of registration in national regulatory agency 21/11/2023 Public title Acronym Long-term Safety and Tolerability of Inclisiran in Participants With HeFH or HoFH Who Have Completed the Adolescent ORION-16 or **ORION-13 Studies** Scientific title Acronym 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) Brief summary of the study: English 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 Brief summary of the study: Arabic دراسة تمديد مفتوحة التسمية ومتعددة المراكز من مجموعة واحدة لتقييم سلامة إنكليسيران وقدرة تحمله على المدى الطويل لدي مشاركين - أو دراسة أوريون (ÖRION-16) 16مصابين بفرط كوليسترول الدم العائلي متغاير الزيجوت أو متماتل الزيجوت أنجزوا دراسة أوريون-(VICTORION-PEDS-OLE) للمراهقين (VICTORION-PEDS-OLE) Health conditions/problem studied: Specify Heterozygous or Homozygous Familial Hypercholesterolemia Interventions: Specify Drug: Inclisiran Inclisiran sodium 300mg (equivalent to 284mg inclisiran*) in 1.5mL solution administered subcutaneously in pre-filled syringe

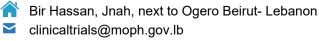


Other Name: KJX839



Key inclusion and exclusion criteria: Inclusion 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 inclusion and exclusion criteria: Gender Both	Key inclusion and exclusion criteria: Specify gender		
Key inclusion and exclusion criteria: Age minimum 12	Key inclusion and exclusion criteria: Age maximum 17		
Key inclusion and exclusion criteria: Exclusion criteria Key exclusion:			
1- Participants who in the feeder inclisiran ORION-16 and ORION-13 studies treatment/study for any reason or had serious safety or tolerability issues rela 2- Any uncontrolled or serious disease, or any medical, physical, or surgical study or interpretation of clinical study results, and/or put the participant at si	ated to inclisiran treatment condition, that may either interfere with participation in the clinical		
Type of study Interventional			
Type of intervention Pharmaceutical	Type of intervention: Specify type N/A		
Trial scope Therapy	Trial scope: Specify scope N/A		
Study design: Allocation Single Arm Study	Study design: Masking Open (masking not used)		
Study design: Control N/A	Study phase 3		
Study design: Purpose Treatment	Study design: Specify purpose N/A		
Study design: Assignment Single	Study design: Specify assignment N/A		
IMP has market authorization Yes, Worldwide	IMP has market authorization: Specify European Union, United Arab Emirates, Great Britain		
Name of IMP Inclisiran	Year of authorization Month of authorization		
Type of IMP Others			
Pharmaceutical class Cholesterol-lowering small interfering ribonucleic acid (siRNA) that inhibits the convertase subtilisin/kexin type 9 (PCSK9) Therapeutic indication Heterozygous or Homozygous Familial Hypercholesterolemia	e production of proprotein		

Therapeutic benefit





Treatment	
Study model N/A	Study model: Explain model N/A
Study model: Specify model N/A	
Time perspective N/A	Time perspective: Explain time perspective N/A
Time perspective: Specify perspective N/A	
Target follow-up duration	Target follow-up duration: Unit
Number of groups/cohorts	
Biospecimen retention Samples without DNA	Biospecimen description Blood samples collected will be analyzed at Medpace Laboratories, central Lab
Target sample size	Actual enrollment target size
Date of first enrollment: Type Anticipated	Date of first enrollment: Date 30/08/2023
Date of study closure: Type Anticipated	Date of study closure: Date 30/08/2026
Recruitment status Pending	Recruitment status: Specify
Date of completion	
IPD sharing statement plan	IPD sharing statement description
Yes	Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.
Additional data URL	This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com



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https://clinicaltrials.gov/ct2/show/record/NCT05682378

Admin comments

Trial status

Approved

Secondary Identifying Numbers		
Full name of issuing authority	Secondary identifying number	
clinical trials.gov	NCT05682378	

Sources of Monetary or Material Support

Name

Novartis Pharma AG

Se	econdary Sponsors
Nan	me
NA	

Contact for Public/Scientific Queries						
Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Selim Jambart	Beirut	Lebanon	009613406 001	sjambart@dm.ne t.lb	Hotel Dieu De France
Scientific	Hind Khairallah	Sin El Fil	Lebanon	009611512 002 Ext. 271 E	hind.khairallah@f attal.com.lb	khalil Fattal et Fils s.a.l

Centers/Hospitals Involved in the Study			
Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu De France	Selim Jambart	Endocrinology	Approved





Ethics Review				
Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	30/03/2023	Sami Richa	cue@usj.edu.lb	00961421229

Countries of Recruitment
Name
Lebanon
Brazil
Canada
France
Germany
Greece
Hungary
Italy
Netherlands
Norway
Poland
Russian Federation
Slovenia
Spain
Switzerland
United States of America

Health Conditions or Problems Studied		
Condition	Code	Keyword
Heterozygous or homozygous familial hypercholesterolemia	Hyperlipidaemia, unspecified (E78.5)	Heterozygous or homozygous familial hypercholesterolemia

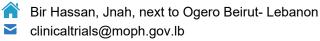




Interventions		
Intervention	Description	Keyword
Consenting, IMP administration, Laboratory testing, Imaging	Consenting, IMP administration, Laboratory testing, Imaging	Consenting, IMP administration, Laboratory testing, Imaging

Primary Outcomes		
Name	Time Points	Measure
Number of participants with treatment-emergent adverse events (TEAEs) and serious adverse events (TESAEs)	Time Frame: From Day 1 in the study up to the end of study visit; up to 1080 days	Safety and tolerability: TEAEs, TESAEs (incidence, severity, relationship to study drug and discontinuation due to TEAEs)

Key Secondary Outcomes		
Name	Time Points	Measure
Percentage and absolute change in LDL-C from baseline in the feeder study to end of study	Time Frame: Baseline (of feeder study) and Day 1080	Evaluate the long-term effect of inclisiran (from baseline of feeder study to end of study) in lowering LDL-C





Trial Results Summary results Study results globally Date of posting of results summaries Date of posting of results summaries Date of first journal publication of results Results URL link Baseline characteristics Participant flow Adverse events Outcome measures URL to protocol files