KURZPROTOKOLL
ORION-8

Öffentlicher Titel	Phase III Studie zu Inclisiran bei Patienten mit hohem kardiovaskulärem Risiko und erhöhtem LDL-C
Wissenschaftl. Titel	A long term extension trial of the Phase III lipid-lowering trials to assess the effect of long -term dosing of inclisiran given as subcutaneous injections in subjects with high cardiovascular risk and elevated LDL-C (ORION-8)
Kurztitel	ORION-8
Studienart	multizentrisch, prospektiv, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase III
Erkrankung	Herz und Kreislauf: sonstige Herz und Kreislauf: Schlaganfall / Hirninfarkt Herz und Kreislauf: Herzinsuffizienz
Einschlusskriterien	- Completion of a previously qualifying Phase III lipid-lowering ORION feeder study [MDCO-PCS-17-03 (ORION-9), MDCO-PCS-17-04 (ORION-10), MDCO-PCS-17-08 (ORION-11) or MDCO-PCS-17-02 (ORION-5)] meaning the subject received the last dose of study drug and completed the final study visit per applicable protocol. - On current lipid-lowering therapies (such as a statin and/or ezetimibe) from previous study with no planned medication or dose change during study participation. - Willing and able to give informed consent before initiation of any study-related procedures and willing to comply with all required study procedures.
Ausschlusskriterien	- Any uncontrolled or serious disease, or any medical or surgical condition, that may either interfere with participation in the clinical study, and/or put the subject at significant risk [according to investigator's (or delegate's) judgment] if he/she participates in the clinical study. - An underlying known disease, or surgical, physical, or medical condition that, in the opinion of the investigator (or delegate) might interfere with interpretation of the clinical study results. - Severe concomitant noncardiovascular disease that carries the risk of reducing life expectancy to less than 3 years - Active liver disease defined as any known current infectious, neoplastic, or metabolic pathology of the liver or unexplained alanine aminotransferase (ALT), aspartate aminotransferase (AST), elevation >3x the upper limit of normal (ULN), or total bilirubin (TBIL) elevation >2x ULN at the last recorded visit in the feeder study prior to study entry visit. - Females who are pregnant or nursing, or who are of childbearing potential and unwilling to use at least one method of acceptable effective contraception (eg, oral contraceptives, barrier methods, approved contraceptive implant, long-term injectable contraception, intrauterine device) for the entire duration of the study. Exemptions from this criterion: a) Women >2 years postmenopausal (defined as 1 year or longer since last menstrual period) and more than 55 years of age. b) Postmenopausal women (as defined above) and less than 55 years of age with a negative pregnancy test within 24 hours of randomization. c) Women who are surgically sterilized at least 3 months prior to enrollment. - Planned use of other investigational medicinal products other than inclisiran or devices during the course of the study.

	- Any condition that according to the investigator could interfere with the conduct of the study, such as but not limited to: a) Subjects who are unable to communicate or to cooperate with the investigator b) Unable to understand the protocol requirements, instructions and study-related restrictions, the nature, scope, and possible consequences of the study (including subjects whose cooperation is doubtful due to drug abuse or alcohol dependency) c) Unlikely to comply with the protocol requirements, instructions, and study-related restrictions (eg, uncooperative attitude, inability to return for follow-up visits, and improbability of completing the study) d) Have any medical or surgical condition, which in the opinion of the investigator would put the subject at increased risk from participating in the study e) Persons directly involved in the conduct of the study.
Alter	18 Jahre und älter
Sponsor	Novartis Pharma
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03814187 EudraCT 2017-003092-55 (primäres Register)