RAVIMIAMET

Alexander Kainz
Novartis Pharma AG
Roonstrasse 25
90429 Nürnberg
GERMANY

02.07.2024 nr RKU-4/42

DECISION

to grant authorisation for clinical trial on the basis of Regulation (EU) No 536/2014 of the European Parliament and of the council

State Agency of Medicines has received the application from sponsor Novartis Pharma AG on 17.05.2024 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99^1 (1) of Estonian Medicinal Products Act (MPA).

Based on art 8 of Regulation (EU) No 536/2014, considering the aspects covered by Part I and Part II of the assessment report, on the basis of § 99^6 section 1 p 1 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no CKJX839B12302 under the following conditions:

protocol no: CKJX839B12302 (Version 2.0, dated 10 July 2023)

full title of the trial: A randomized, double-blind, placebo -controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT)

sponsor of the trial: Novartis Pharma AG

number of subjects in Estonia: 67

principal investigators and study locations:
- Dr Liina Viitas – Liina Viitas OU, Veetorni 2-1, 80018 Pärnu, Estonia
- Dr Jaak Tälli – Innomedica OU, Narva 7, 10117 Tallinn, Estonia
- Dr Heli Kaljusaar – East-Tallinn Central Hospital, Ravi 18, 10138 Tallinn, Estonia
- Dr Eno-Martin Lotman – North-Estonia Medical Centre Foundation, J. Sütiste 19, 13419 Tallinn, Estonia
- Dr Lidia Rändvee – Medicum Healthcare Institution, Punane 61, 13619 Tallinn, Estonia
- Dr Arvo Rosenthal – Dr Arvo Rosenthal OU, J. Sütiste 19a-198, 13419 Tallinn, Estonia
- Dr Eve Laane – Tartu University Hospital, L. Puusepa 8, 50406 Tartu, Estonia

- Dr Raili Müller – MediTrials OU, Mõisavahe 34c, 50708 Tartu, Estonia

The addressee may file a challenge with State Agency of Medicines within 30 days as of the day when the addressee became or should have become aware of the decision as prescribed in Code of Administrative Procedure § 71(1). If the addressee wishes to have the decision to annulled by the administrative court, he or she may submit a complaint to the Tartu Administrative Court as prescribed in § 7(1) and § 46(1) of the Code of Administrative Court Procedure within 30 days after the date on which the decision was notified to the applicant.

(digitally signed)

Katrin Kiisk
Director General