RAVIMIAMET

Alexander Kainz
Novartis Pharma AG
Lichtstrasse 35
4056 Basel
SWITZERLAND

18.07.2024 nr RKU-4/47

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 27.05.2024 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 CKJX839A12402 under the following conditions:

protocol no: CKJX839A12402 (Version 02, dated November 1, 2022)

full title of the trial: Efficacy, safety, tolerability and quality of life of ongoing individually optimized lipid-lowering therapy with or without inclisiran (KJX839) – a randomized, placebo-controlled, double-blind multicenter phase IV study in participants with hypercholesterolemia

sponsor of the trial: Novartis Pharma AG

number of subjects in Estonia: 94

principal investigators and study locations:
- Dr Arvo Rosenthal, Dr Arvo Rosenthal OÜ, J. Sütiste tee 19a-198, 13419 Tallinn, Estonia
- Dr Piret Härma-Jõks, East Tallinn Central Hospital, Ravi tn 18, 10138 Tallinn, Estonia
- Dr Eve Laane, Tartu University Hospital, L. Puusepa tn 1a, 50406 Tartu, Estonia
- Dr Riina Vettus, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Liina Viitas, Liina Viitas OÜ, Veetorni 2-1, 80018 Pärnu, 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)

Ott Laius
Deputy Director General
on duties of Director General