RAVIMIAMET

Amgen Europe B.V contact point for union
Amgen Europe B.V.
Minervum 7061
4817 ZK Breda
THE NETHERLANDS

11.04.2024 nr RKU-4/25

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 Amgen Inc. on 28.02.2024 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 20170625 under the following conditions:

protocol no: 20170625 (Version 6, dated June 12, 2023)

full title of the trial: A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Evaluate the Impact of Evolocumab on Major Cardiovascular Events in Patients at High Cardiovascular Risk Without Prior Myocardial Infarction or Stroke

sponsor of the trial: Amgen Inc.

number of subjects in Estonia: 63

principal investigators and study locations:
- Dr Arvo Rosenthal, Dr Arvo Rosenthal OÜ, J. Sütiste tee 19a-198, 13419 Tallinn, Estonia
- Dr Ivo Valter, Center for Clinical and Basic Research AS, J. Pärna tn 4, 10128 Tallinn, Estonia
- Dr Marika Paumets, 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)

Katrin Kiisk
Director General