RAVIMIAMET

Opthea Limited
650 Chapel Street
3141 South Yarra
AUSTRALIA

02.09.2024 nr RKU-4/65

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 Opthea Limited on 26.07.2024 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 2 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no OPT-302-1005 under the following conditions:

protocol no: OPT-302-1005 (Version 2.0 AM.1, dated December 19, 2023)

full title of the trial: A Phase 3, Multicentre, Double-masked, Randomised Study to Evaluate the Efficacy and Safety of Intravitreal OPT-302 in Combination with Aflibercept, Compared with Aflibercept Alone, in Participants with Neovascular Age-related Macular Degeneration (nAMD)

sponsor of the trial: Opthea Limited

number of subjects in Estonia: 16

principal investigators and study locations:
- Dr Kai Noor, Silmalaser OÜ, Katusepapi tn 6, 11412 Tallinn, Estonia
- Dr Krista Turman, Silmaarst Krista Turman OÜ, Järve tn 2, 11314 Tallinn, Estonia
- Dr Kadi Palumaa, East Tallinn Central Hospital, Ravi tn 18, 10138 Tallinn, 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