REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Unofficial translation of 08.06.2026 Decision RKU4/13

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 Eyebiotech Limited, represented in these proceedings by MSD Sharp & Dohme GmbH, on 05.02.2026 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 MK-8748-002 under the following conditions:

protocol no:	MK-8748-002 (Version 1.2 EU, dated 26.05.2026)
EU CT nr:	2025-524575-22-00
full title of the trial:	A randomized double-masked, multicenter, 3-arm, pivotal Phase 2/3 study to evaluate the efficacy and safety of intravitreal (IVT) EYE201/MK-8748 compared to aflibercept (2 mg) in participants with neovascular age-related macular degeneration (NVAMD)
sponsor of the trial:	Eyebiotech Limited
number of subjects in Estonia:	20
starting date:	June 2026

principal investigators and study locations:
- Kadi Palumaa, AS Ida-Tallinna Keskhaigla (East Tallinn Central Hospital), Ravi 18, 10138 Tallinn, Estonia
- Kai Noor, Silmalaser OÜ, Katusepapi 6, 11412 Tallinn, Estonia
- Kaie Kaasik, SA Tartu Ülikooli Kliinikum (Tartu University Hospital), Puusepa 8, A006, 50406 Tartu, Estonia
- Krista Turman, Silmaarst Krista Turman OÜ, Järve 2, 10120 Tallinn, Estonia

According to § 71(1) and § 75 of the Administrative Procedure Act a challenge to this decision may be filed within 30 days as from notification of the decision. Where the recipient wishes to contest the decision in administrative court, he or she may in accordance with the Code of Administrative Court Procedure § 7 subsection 1 and 46 subsection 1 file complaint against the decision to Tartu Administrative Court within 30 days as from notification of the decision.