REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Unofficial translation of 23.11.2026 Decision RKU4/33

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 Vertex Pharmaceuticals Inc. represented in these proceedings by Vertex Pharmaceuticals (Ireland) Limited, on 03.08.2026 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 VX25-AIS-102 under the following conditions:

protocol no:	VX25-AIS-102 (Version 3.1 (EU), dated 28.10.2026)
EU CT number:	2025-525064-14-00
full title of the trial:	A Phase 3, Single-Arm, Open-Label Extension Study Evaluating the Long-Term Safety and Efficacy of Povetacicept in Adults With Immunoglobulin A Nephropathy
sponsor of the trial:	Vertex Pharmaceuticals Inc.
number of subjects in Estonia:	2
starting date:	January 2027

principal investigators and study locations:
- Mai Rosenberg, Tartu University Hospital (Tartu Ülikooli Kliinikum SA), L. Puusepa 8, 50406 Tartu, Estonia
- Kadri Lilienthal, North Estonia Medical Centre Foundation (Põhja-Eesti Regionaalhaigla SA), J. Sütiste Tee 19, 13419 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.