REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Unofficial translation of 23.11.2026 Decision RKU4/32

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 Aurinia Pharmaceuticals Inc., represented in these proceedings by Biomapas UAB, on 24.08.2026 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 14 (1).

Based on art 14(3) and (4) of Regulation (EU) No 536/2014, and Section 99^6(1)(1) and (3) of the Medicines Act, taking into account the reporting Member State's conclusion regarding Part I of the assessment report and evaluating compliance with the requirements set forth in Article 7(1) of the Regulation in Estonia,

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no AUR-200-2024-02 under the following conditions:

protocol no:	AUR-200-2024-02 (Amendment 3: Version 4.0, dated 09.04.2026)
EU CT number:	2025-525127-27-00
full title of the trial:	A Double-Blind, Randomized, Placebo-Controlled Study to Investigate the Safety and Efficacy of Aritinercept, a Dual BAFF/APRIL Inhibitor, in Patients with Generalized Myasthenia Gravis
sponsor of the trial:	Aurinia Pharmaceuticals Inc.
number of subjects in Estonia:	2
starting date:	November 2026

principal investigators and study locations:
- Dr. Liis Väli, Tartu University Hospital (Tartu Ülikooli Kliinikum SA), L. Puusepa 8, 50406 Tartu, Estonia
- Dr. Katrin Gross-Paju, Clinic4U OÜ, Kotka 12 C, 11315 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.