



Unofficial translation of 18.05.2026 Decision RKU4/8

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 Takeda Development Center Americas Inc. on 30.01.2026 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99¹ (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 § 99⁶ 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 TAK-279-PsA-3003 under the following conditions:

protocol no: TAK-279-PsA-3003 (Version Original, dated 19.09.2025)

EU CT number: 2025-522586-30-00

full title of the trial: A Phase 3, Multicenter, Long-Term Extension Study to Evaluate the Long-Term Safety, Tolerability, and Efficacy of Zasocitinib (TAK-279) in Subjects With Active Psoriatic Arthritis Who are Either Biologic DMARD-Naïve or Biologic DMARD-Experienced, Including Those With Inadequate Response to Biologic DMARDs

sponsor of the trial: Takeda Development Center Americas Inc.

number of subjects in Estonia: 24

starting date: July 2026

principal investigators and study locations:

- Dr. Sandra Meisalu, Innomedica OÜ, Narva mnt 7, 10117 Tallinn, Eesti
- Dr. Raili Müller, MediTrials OÜ, Mõisavahe 34c, 50708 Tartu, Eesti
- Dr. Airi Pöder, Kliiniliste Uuringute Keskus OÜ, Sõbra 54/1, 50106 Tartu, Eesti
- Dr. Eve-Kai Raussi, SA Põhja-Eesti Regionaalhaigla, J. Sütiste tee 19, 13419 Tallinn, Eesti

– Dr. Ivo Velter, Center for Clinical and Basic Research AS, J. Pärna 4, 10128 Tallinn, Eesti

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.