



Unofficial translation of 22.06.2026 Decision RKU4/14

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 Odense University Hospital on 27.02.2026 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 64007957MMY2022 under the following conditions:

protocol no: 64007957MMY2022 (Version 1, dated 19.05.2025)

EU CT number: 2025-522114-23-00

full title of the trial: A Phase II, Open-label, Multicenter Study Testing Teclistamab in Combination with Pomalidomide Administered in Alternative Fashion in Participants with RRMM, who Received 1 - 3 Prior Lines of Therapy, Including Lenalidomide and Anti-CD38 Therapy

sponsor of the trial: Odense University Hospital

number of subjects in Estonia: 15

starting date: June 2026

principal investigators and study locations:

- Dr. Diana Loigom, SA Põhja-Eesti Regionaalhaigla (North Estonia Medical Centre Foundation), J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr. Maris Pärnat, SA Tartu Ülikooli Kliinikum (Tartu University Hospital), L. Puusepa 1a, 50406 Tartu, 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.