REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Unofficial translation of 14.09.2026 Decision RKU4/24

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 Argenx on 30.06.2026 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 ARGX-113-15-SjD-2003 under the following conditions:

protocol no:	ARGX-113-15-SjD-2003 (Version 2.0, dated 14.08.2026)
EU CT number:	2026-526218-10-00
full title of the trial:	A Phase 2, Randomized, Double-Blinded, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Efgartigimod PH20 Subcutaneous Administered by Prefilled Syringe in Adult Participants with Sjogren's Disease-Associated Sensorimotor or Sensory Polyneuropathy
sponsor of the trial:	Argenx
number of subjects in Estonia:	4
starting date:	October 2026

principal investigators and study locations:
- Dr. Sandra Meisalu, Innomedica OÜ, Narva mnt 7, 10117 Tallinn, Estonia
- Dr. Ivo Valter, Center for Clinical and Basic Research AS, J. Pärna 4, 10128 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.