



Unofficial translation of 13.07.2026 Decision RKU4/16

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 Sanofi-Aventis Recherche & Developpement on 16.03.2026 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 2 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no EFC18243-PERSEPHONE under the following conditions:

protocol no:	EFC18243-PERSEPHONE (Version 2, dated 08.06.2026)
EU CT number:	2024-518016-39-00
full title of the trial:	A Phase 2b/Phase 3, randomized, double-blind, placebo-controlled, multicenter study, to investigate the efficacy and safety of lunsekimig in adult participants with inadequately controlled chronic obstructive pulmonary disease (COPD) characterized by an eosinophilic phenotype
sponsor of the trial:	Sanofi-Aventis Recherche & Developpement
number of subjects in Estonia:	8
starting date:	July 2026
principal investigators and study locations:	– Dr. Rain Jõgi, SA Tartu Ülikooli Kliinikum (Tartu University Hospital), L. Puusepa 1a, 50406 Tartu, 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.