REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Unofficial translation of 16.11.2026 Decision RKU4/30

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 Vanda Pharmaceuticals Inc., represented in these proceedings by QPS Netherlands B.V., on 17.07.2026 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 VP-VSP-128-3201 under the following conditions:

protocol no:	VP-VSP-128-3201 (Version 6.2, dated 05.112026)
EU CT number:	2025-524520-22-00
full title of the trial:	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Ponesimod in Patients with Moderately to Severely Active Ulcerative Colitis
sponsor of the trial:	Vanda Pharmaceuticals Inc.
number of subjects in Estonia:	17
starting date:	November 2026

principal investigators and study locations:
- Dr. Julia Borissova, Aktsiaselts Medicum Tervishoiuteenused, Punane 61, 13619 Tallinn, Estonia
- Dr. Leana Sits, Sihtasutus Pärnu Haigla, Ristiku 1, 80010 Pärnu, Estonia
- Dr. Jaak Tälli, Innomedica OÜ, Narva Mnt 7, 10117 Tallinn, Estonia
- Dr. Küllike Palk, North Estonia Medical Centre Foundation (SA Põhja-Tallina Regionaalhaigla), J. Sütiste Tee 19, 13419 Tallinn, Estonia

– Dr. Peeter Kõiva, East Tallinn Central Hospital (AS Ida-Tallinna Keskhaigla), Ravi 18, 10138 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.