REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Unofficial translation of 23.07.2026 Decision RKU4/18

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 Zealand Pharma A/S on 08.05.2026 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 ZP1848-23029 under the following conditions:

protocol no:	ZP1848-23029 (Version 4.0, dated 05.12.2025)
EU CT number:	2024-512486-14-00
full title of the trial:	A Phase 3, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Multicenter Trial to Confirm the Efficacy and Safety of Glepaglutide 10 mg Twice-Weekly, Followed by a Long-Term, Open-Label Safety Evaluation in Patients with Short Bowel Syndrome–Intestinal Failure (SBS-IF)
sponsor of the trial:	Zealand Pharma A/S
number of subjects in Estonia:	3
starting date:	July 2026

principal investigators and study locations:

- Dr. Hanna-Liis Lepp, SA Põhja-Eesti Regionaalhaigla (North Estonia Medical Centre Foundation), J. Sütiste Tee 19, 13419 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.