



Unofficial translation of 09.10.2026 Decision RKU4/29

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 Zydus Therapeutics Inc., represented in these proceedings by Clinical Technology Centre (Ireland) Limited, on 12.06.2026 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 SARO.23.001 under the following conditions:

- | | |
|--|---|
| protocol no: | SARO.23.001 (Version 5.0, dated 11.05.2026) |
| EU CT number: | 2025-524067-20-00 |
| full title of the trial: | A Phase 3b/4, Multicenter, Parallel-Group, Double-Blind, Placebo-Controlled, Two-Arm, Long-Term Study to Evaluate the Safety and Efficacy of Saroglitazar Magnesium on Clinical Outcomes in Participants with Primary Biliary Cholangitis (PBC) |
| sponsor of the trial: | Zydus Therapeutics Inc. |
| number of subjects in Estonia: | 6 |
| starting date: | October 2026 |
| principal investigators and study locations: | |
| | – Dr. Peeter Kõiva, East Tallinn Central Hospital, Ravi 18, 10138 Tallinn, Estonia |
| | – Dr. Julia Borissova, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia |
| | – Dr. Karin Kull, Tartu University Hospital, L. Puusepa 8, 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.