



**Unofficial translation of 29.06.2026 Decision RKU4/15**

**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 Zenas Biopharma (USA) LLC, represented in these proceedings by ICON Clinical Research Ltd, on 27.02.2026 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99<sup>1</sup> (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<sup>6</sup> 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 ZB020-03-002 under the following conditions:

protocol no: ZB020-03-002 (Version V4.1-EU, dated 26.05.2026)

EU CT number: 2025-524322-18-00

full title of the trial: A Phase 3, Randomized, Double-blind, Efficacy and Safety Study Comparing Orelabrutinib to Placebo in Patients With Non-Active Secondary Progressive Multiple Sclerosis

sponsor of the trial: Zenas Biopharma (USA) LLC

number of subjects in Estonia: 3

starting date: June 2026

principal investigators and study locations:

- Dr. Katrin Gross-Paju, Clinic4U OÜ, Kotka 12 C, 11315 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.