



RAVIMIAMET

Global Regulatory Submissions  
Fortrea Development Ltd.  
5 Foundation Park Roxborough Way  
SL6 3UD Maidenhead  
UNITED KINGDOM

24.01.2025 nr RKU-4/4

## DECISION

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 Alumis Inc. on 18.09.2024 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 ESK-001-017 under the following conditions:

**protocol no:** ESK-001-017 (Version 2.1, dated December 11, 2024)

**full title of the trial:** A Multicenter, Randomized, Double-Blind, Placebo and Active Comparator Controlled Phase 3 Study in Patients with Moderate to Severe Plaque Psoriasis to Evaluate the Efficacy and Safety of ESK-001 (ONWARD2)

**sponsor of the trial:** Alumis Inc.

**number of subjects in Estonia:** 33

**starting date:** February 2025

**principal investigators and study locations:**

- Dr Ivo Valter, Center for Clinical and Basic Research AS, J. Pärna tn 4, 10128 Tallinn, Estonia
- Dr Külli Kingo, Tartu University Hospital, Raja tn 31, 50417 Tartu, Estonia
- Dr Jaak Tälli, Innomedica OÜ, Narva mnt 7, 10117 Tallinn, Estonia
- Dr Airi Pöder, Kliiniliste Uuringute Keskus OÜ, Sõbra tn 54/1, 50106 Tartu, Estonia

The addressee may file a challenge with State Agency of Medicines within 30 days as of the day when the addressee became or should have become aware of the decision as prescribed in

Code of Administrative Procedure § 71(1). If the addressee wishes to have the decision to annulled by the administrative court, he or she may submit a complaint to the Tartu Administrative Court as prescribed in § 7(1) and § 46(1) of the Code of Administrative Court Procedure within 30 days after the date on which the decision was notified to the applicant.

(digitally signed)

Katrin Kiisk  
Director General