



RAVIMIAMET

Olesya Kanievshchynska
UAB Biomapas
K. Donelaicio str. 60
LT-44248 Kaunas
LITHUANIA

18.11.2024 nr RRU-4/85

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 Alpine Immune Sciences Inc. on 26.07.2024 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 1 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no AIS-D08 under the following conditions:

protocol no: AIS-D08 (Version 3.4 (EU), dated October 17, 2024)

full title of the trial: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Povetacept in Adults with Immunoglobulin A Nephropathy (RAINIER).

sponsor of the trial: Alpine Immune Sciences Inc.

number of subjects in Estonia: 4

starting date: November 2024

principal investigators and study locations:

- Dr Mai Rosenberg, Tartu University Hospital, L. Puusepa tn 8, 50406 Tartu, Estonia
- Dr Kadri Lilienthal, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, 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