



RAVIMIAMET

Tracy Klenk
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Stationsplein-NO 438
1117CL, Schiphol
THE NETHERLANDS

11.03.2024 nr RKU-4/17

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 Anaptysbio Inc. on 25.10.2023 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 ANB030-2023 under the following conditions:

protocol no: ANB030-2023 (Version 3.2, dated February 27, 2024)

full title of the trial: A Phase 2, Randomized, Double Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Rosnilimab in Subjects with Moderate to Severe Rheumatoid Arthritis

sponsor of the trial: Anaptysbio Inc.

number of subjects in Estonia: 8

starting date: March 2024

principal investigators and study locations:

- Dr Sandra Meisalu, Innomedica OÜ, Narva mnt 7, 10117 Tallinn, Estonia
- Dr Ene Ojassalu, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Airi Põder, 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