RAVIMIAMET

Jamil Ahmad
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UNITED KINGDOM

02.04.2024 nr RKU-4/24

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 Anthos Therapeutics Inc. on 12.01.2024 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99^1 (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 § 99^6 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 ANT-010 under the following conditions:

protocol no: ANT-010 (Version 4.1, dated September 29, 2023)

full title of the trial: A Phase 3, multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaLuate the effIcacy and safety of abeLacimab in high-risk patients with Atrial fibrillation who have been deemed unsuitable for oral antiCoagulation (LILAC)

sponsor of the trial: Anthos Therapeutics Inc.

number of subjects in Estonia: 18

starting date: April 2024

principal investigators and study locations:
- Dr Eno-Martin Lotman, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Katrin Gross-Paju, Lääne-Tallinna Keskhaigla AS, Paldiski Mnt 68, 10617 Tallinn, Estonia
- Dr Inga Kalju, East Tallinn Central Hospital, Ravi tn 18, 10138 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