RAVIMIAMET

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Worldwide Clinical Trials Limited
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UNITED KINGDOM

10.01.2025 nr RKU-4/1

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 Angitia Inc. Ltd. on 06.09.2024 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 ACT23-001 under the following conditions:

protocol no: ACT23-001 (Version 3.1, dated November 22, 2024)

full title of the trial: A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Finding Study to Evaluate the Safety, Tolerability and Efficacy of AGA2118 in Postmenopausal Women with Low Bone Mineral Density

sponsor of the trial: Angitia Inc. Ltd.

number of subjects in Estonia: 25

starting date: the conditions to start the trial are specified within Clinical Trials Information System (CTIS) under EU CT 2024-515610-41-00, application ID 28895

principal investigators and study locations:
- Dr Raili Müller, MediTrials OÜ, Mõisavahe tn 34c, 50708 Tartu, Estonia
- Dr Ivo Valter, Center for Clinical and Basic Research AS, J. Pärna tn 4, 10128 Tallinn, Estonia
- Dr Andres Pille, East Tallinn Central Hospital, Pärnu mnt 104, 11312 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