RAVIMIAMET

Jaanus Korjas
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50411 Tartu
ESTONIA

02.04.2024 nr RKU-4/23

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 University of Tartu on 23.12.2023 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 1 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no PONVApr1 under the following conditions:

protocol no: PONVApr1 (Version 2, dated March 25, 2024)

full title of the trial: The efficacy of aprepitant for the prevention of postoperative nausea and vomiting after bariatric surgery

sponsor of the trial: University of Tartu

number of subjects in Estonia: 260

starting date: April 2024

principal investigators and study locations:

- Dr Jaanus Korjas, AS Bariatric Services, Kaluri tee 5a, 74001 Viimsi vald, 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