



RAVIMIAMET

Rita Kuzminiene
AbbVie OÜ
Rävala 4
10145 Tallinn
ESTONIA

18.11.2024 nr RKU-4/87

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 AbbVie Deutschland GmbH & Co. KG on 17.07.2024 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 M24-885 under the following conditions:

protocol no: M24-885 (Version 1.2.1, dated November 06, 2024)

full title of the trial: A Phase 2a Multicenter, Randomized, Platform Study of Targeted Therapies for the Treatment of Adult Subjects with Moderate to Severe Crohn's Disease

sponsor of the trial: AbbVie Deutschland GmbH & Co. KG

number of subjects in Estonia: 12

starting date: November 2024

principal investigators and study locations:

- Dr Thomas Zimmerer, East Tallinn Central Hospital, Ravi tn 18, 10138 Tallinn, Estonia
- Dr Karin Kull, Tartu University Hospital, L. Puusepa tn 1a, 50406 Tartu, Estonia
- Dr Julia Borissova, Aktsiaselts Medicum Tervishoiuteenus, Punane tn 61, 13619 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