



RAVIMIAMET

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Rävala 4  
10145 Tallinn  
ESTONIA

21.06.2024 nr RKU-4/41

## 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 13.05.2024 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99<sup>1</sup> (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<sup>6</sup> 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 M16-000 under the following conditions:

**protocol no:** M16-000 (Version 10.1, dated July 28, 2023)

**full title of the trial:** A Multicenter, Randomized, Double-Blind, Placebo- Controlled 52-Week Maintenance and an Open-Label Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Crohn's Disease

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

**number of subjects in Estonia:** 4

**principal investigators and study locations:**

- Dr Julia Borissova, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Thomas Zimmerer, East Tallinn Central Hospital, Ravi tn 18, 10138 Tallinn, Estonia
- Dr Külliki Suurmaa, Lääne-Tallinna Keskhaigla AS, Paldiski mnt 68, 10617 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