



RAVIMIAMET

Rita Kuzminiene  
AbbVie OÜ  
Rävala 4  
10145 Tallinn  
ESTONIA

24.07.2024 nr RKU-4/54

## 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 02.04.2024 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 M23-703 under the following conditions:

**protocol no:** M23-703 (Version 2.1.1, dated July 12, 2024)

**full title of the trial:** A Multicenter, Randomized Study to Evaluate the Safety and Efficacy of Lutikizumab for Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis

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

**number of subjects in Estonia:** 4

**starting date:** August 2024

**principal investigators and study locations:**

- Dr Leana Sits, sihtasutus Pärnu Haigla, Ristiku tn 1, 80010 Pärnu, Estonia
- Dr Külliki Suurmaa, Lääne-Tallinna Keskhaigla AS, Paldiski mnt 68, 10617 Tallinn, Estonia
- Dr Julia Borissova, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Karin Kull, Tartu University Hospital, L. Puusepa tn 1a, 50406 Tartu, 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