



RAVIMIAMET

Kristina Marsh
AbbVie OU
Rävala 4
10145 Tallinn
ESTONIA

05.03.2024 nr RKU-4/16

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 22.01.2024 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 **M16-011** under the following conditions:

protocol no: M16-011 (Version 6.0, dated 13 March 2023)

full title of the trial: A Phase 3, Randomized, Double-Blind, Study Comparing Risankizumab to Placebo in Subjects with Active Psoriatic Arthritis (PsA) Who Have a History of Inadequate Response to or intolerance to at Least One Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy

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

number of subjects in Estonia: 19

principal investigators and study locations:

- Dr Raili Müller – MediTrials OU, Mõisavahe 34c, 50708 Tartu, Estonia
- Dr Sandra Meisalu – Innomedica OU, Narva 7, 10117 Tallinn, Estonia
- Dr Eve-Kai Raussi – North Estonia Medical Centre Foundation, J. Sütsite 19, 13419 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