RAVIMIAMET

Aleksandra Jankielewicz
AbbVie Deutschland GmbH & Co. KG
Knollstrasse
67061 Ludwigshafen Am Rhein
GERMANY

05.03.2024 nr RKU-4/20

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 19.01.2024 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 M15-998 under the following conditions:

protocol no: M15-998 (Version 7.0, dated March 13, 2023)

full title of the trial: A Phase 3, Randomized, Double-Blind Study Comparing Risankizumab to Placebo in Subjects with Active Psoriatic Arthritis Including Those Who Have a History of Inadequate Response or Intolerance to Biologic Therapy(ies) (KEEPsAKE 2)

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

number of subjects in Estonia: 11

principal investigators and study locations:
- Dr Eve Kai Raussi, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Tiina Veldi, East Tallinn Central Hospital, Pärnu Mnt 104, 11312 Tallinn, Estonia
- Dr Raili Müller, MediTrials OÜ, Mõisavahe Tn 34c, 50708 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