RAVIMIAMET

Janssen - Cilag International
Turnhoutseweg 30
2340 Beerse
BELGIUM

25.07.2024 nr RKU-4/53

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 Janssen - Cilag International on 21.06.2024 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 2 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no CNTO1959PSA3004 under the following conditions:

protocol no: CNTO1959PSA3004 (Amendment 2, dated May 04, 2022)

full title of the trial: A Phase 3b, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Subcutaneously Administered Guselkumab in Improving the Signs and Symptoms and Inhibiting Radiographic Progression in Participants with Active Psoriatic Arthritis.

sponsor of the trial: Janssen - Cilag International

number of subjects in Estonia: 10

principal investigators and study locations:
- Dr Eve-Kai Raussi, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Airi Põder, Kliiniliste Uuringute Keskus OÜ, Sõbra tn 54/1, 50106 Tartu, Estonia
- Dr Sandra Meisalu, Innomedica OÜ, Narva mnt 7, 10117 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