RAVIMIAMET

Gabriele Jurksaite
Parexel International
Kestucio 65/40
LT-08124 Vilnius
LITHUANIA

24.05.2024 nr RKU-4/35

**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 15.04.2024 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 78934804CRD2001 under the following conditions:

**protocol no**: 78934804CRD2001 (Version 3.0, dated June 29, 2023)

**full title of the trial**: A Phase 2b Randomized, Double-blind, Active- and Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Induction and Maintenance Combination Therapy with Guselkumab and Golimumab in Participants with Moderately to Severely Active Crohn's Disease

**sponsor of the trial**: Janssen - Cilag International

**number of subjects in Estonia**: 5

**principal investigators and study locations**:
- Dr Karin Kull, Tartu University Hospital, L. Puusepa tn 8, 50406 Tartu, Estonia
- Dr Külliki Suurmaa, Lääne-Tallinna Keskhaigla AS, Paldiski mnt 68, 10617 Tallinn, Estonia
- Dr Peeter Kõiva, East Tallinn Central Hospital, Ravi tn 18, 10138 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)

Ott Laius
Deputy Director General
on duties of Director General