RAVIMIAMET

Optimapharm Nordic Oy
Vaisalantie 4
02130 Espoo
FINLAND

09.05.2024 nr RKU-4/30

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 Glaxosmithkline Research & Development Limited on 20.03.2024 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 219606 under the following conditions:

protocol no: 219606 (Amendment 01, dated June 13, 2023)

full title of the trial: A Phase 3, Open-Label, Randomized Study of Perioperative Dostarlimab Monotherapy versus Standard of Care in Participants with Untreated T4N0 or Stage III dMMR/MSI-H Resectable Colon Cancer

sponsor of the trial: Glaxosmithkline Research & Development Limited

number of subjects in Estonia: 23

starting date: May 2024

principal investigators and study locations:
- Dr Anneli Elme, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Andrus Mägi, Tartu University Hospital, L. Puusepa tn 1a, 50406 Tartu, Estonia
- Dr Elen Vettus, East Tallinn Central Hospital, Pärnu mnt 104, 11312 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