



RAVIMIAMET

Aivi Keldrimaa
Merck Sharp & Dohme OÜ
A.H. Tammsaare tee 47
11316 Tallinn
ESTONIA

22.03.2024 nr RKU-4/18

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 Merck Sharp & Dohme LLC on 10.11.2023 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 (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no MK-5684-004 under the following conditions:

protocol no: MK-5684-004 (Version 03, dated March 14, 2024)

full title of the trial: A Phase 3, Randomized, Open-label Study of MK-5684 Versus Alternative Abiraterone Acetate or Enzalutamide in Participants with Metastatic Castration-resistant Prostate Cancer (mCRPC) That Progressed On or After Prior Treatment with One Next generation Hormonal Agent (NHA)

sponsor of the trial: Merck Sharp & Dohme LLC

number of subjects in Estonia: 15

starting date: March 2024

principal investigators and study locations:

- Dr Helis Pokker, North Estonia Medical Centre Foundation, J. Sütiste Tee 19, 13419 Tallinn, Estonia
- Dr Elen Vettus, East Tallinn Central Hospital, Pärnu Mnt 104, 11312 Tallinn, Estonia
- Dr Marju Kase, Tartu University Hospital, L. Puusepa Tn 8, 50406 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