



RAVIMIAMET

Ligita Ziedone
Merck Sharp & Dohme OÜ
A.H. Tammsaare tee 47
11316 Tallinn
ESTONIA

27.03.2024 nr RKU-4/21

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 24.10.2023 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 2 (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no V940-002 under the following conditions:

protocol no: V940-002 (Version 02, dated March 13, 2024)

full title of the trial: A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With Resected Stage II, IIIA, IIIB (N2) Non-small Cell Lung Cancer

sponsor of the trial: Merck Sharp & Dohme LLC

number of subjects in Estonia: 10

starting date: April 2024

principal investigators and study locations:

- Dr Kersti Oselin, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Jana Jaal, 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