



RAVIMIAMET

Anne-Sylvie Lefebvre Brunel
Moderna Therapeutics Inc.
19 rue Cognacq Jay
75007 Paris
FRANCE

21.02.2024 nr RKU-4/12

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 Moderna Therapeutics Inc. on 15.01.2024 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 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no mRNA1647-P301 under the following conditions:

protocol no: mRNA1647-P301 (Version 3, dated June 15, 2023)

full title of the trial: A Phase 3, Randomized, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1647 Cytomegalovirus (CMV) Vaccine in Healthy Participants 16 to 40 Years of Age

sponsor of the trial: Moderna Therapeutics Inc.

number of subjects in Estonia: 518

principal investigators and study locations:

- Dr Airi Põder, Kliiniliste Uuringute Keskus OÜ, Sõbra tn 54/1, 50106 Tartu, Estonia
- Dr Kaia Kiiroja, Al Mare Perearstikeskus OÜ, Paldiski mnt 68a, 10617 Tallinn, Estonia
- Dr Riin Lanno, Merelahe TK OÜ, Paldiski mnt 68a, 10617 Tallinn, Estonia
- Dr Ivo Valter, Center for Clinical and Basic Research AS, J. Pärna tn 4, 10128 Tallinn, Estonia
- Dr Ingrid Alt, Vee Family Doctors Center Ltd, Vee 6, 72713 Paide, 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