



RAVIMIAMET

Marie-Pierre Caby-Tosi  
Moderna Inc.  
19 Rue Cognacq Jay  
75007 Paris  
FRANCE

14.10.2024 nr RKU-4/81

## 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 Inc. on 13.09.2024 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99<sup>1</sup> (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<sup>6</sup> 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 mRNA-1010-P304 under the following conditions:

**protocol no:** mRNA-1010-P304 (Version 1.0, dated March 14, 2024)

**full title of the trial:** A Phase 3, Randomized, Observer-blind, Active-controlled, Case-driven Study to Investigate the Safety, Efficacy, and Immunogenicity of mRNA-1010 Candidate Seasonal Influenza Vaccine Compared with a Licensed Inactivated Seasonal Influenza Vaccine in Adults  $\geq 50$  Years of Age

**sponsor of the trial:** Moderna Inc.

**number of subjects in Estonia:** 1500

**starting date:** October 2024

principal investigators and study locations:

- Dr Airi Põder, Kliiniliste Uuringute Keskus OÜ, Sõbra tn 54/1, 50106 Tartu, Estonia
- Dr Riin Lanno, Merelahe TK OÜ, Paldiski mnt 68a, 10617 Tallinn, Estonia
- Dr Jaak Tälli, Innomedica OÜ, Narva mnt 7, 10117 Tallinn, Estonia
- Dr Ivo Valter, Center for Clinical and Basic Research AS, J. Pärna tn 4, 10128 Tallinn, Estonia
- Dr Ingrid Alt, Vee Perearstikeskus OÜ, Vee tn 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