RAVIMIAMET

Katrin Peedo
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Narva mnt 3
51009 Tartu
ESTONIA

18.11.2024 nr RKU-4/86

**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 AstraZeneca AB and Icosavax Inc. on 23.07.2024 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 D8610C00001 under the following conditions:

**protocol no**: D8610C00001 (Version 2.0, dated October 17, 2024)

**full title of the trial**: A Phase 3, Global, Randomized, Modified Double-Blind, Placebo-Controlled, Study to Evaluate the Efficacy, Immunogenicity, and Safety of IVX-A12, a Respiratory Syncytial Virus (RSV) and Human Metapneumovirus (hMPV) Virus-Like Particle (VLP) Vaccine in Adults 60 Years of Age and Older.

**sponsor of the trial**: AstraZeneca AB and Icosavax Inc.

**number of subjects in Estonia**: 236

**starting date**: September 2025

**principal investigators and study locations**:
- Dr Airi Põder, Kliiniliste Uuringute Keskus OÜ, Sõbra tn 54/1, 50106 Tartu, Estonia
- Dr Rain Jõgi, Tartu University Hospital, L. Puusepa tn 1a, 50406 Tartu, Estonia
- Dr Riin Lanno, Merelahe TK OÜ, 10617 Tallinn, Estonia
- Dr Ivo Valter, Center for Clinical and Basic Research AS, J. Pärna tn 4, 10128 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