



RAVIMIAMET

Medpace Finland Oy  
Kaikukatu 4 C  
00530 Helsinki  
FINLAND

02.09.2024 nr RKU-4/68

## 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 Meiji Seika Pharma Co. Ltd. on 09.08.2024 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 2 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no OP0595-5 under the following conditions:

**protocol no:** OP0595-5 (Version 5.0, dated December 20, 2023)

**full title of the trial:** A Phase 3, Multi-Center, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Cefepime/Nacubactam or Aztreonam/Nacubactam Compared to Imipenem/Cilastatin in the Treatment of Complicated Urinary Tract Infections or Acute Uncomplicated Pyelonephritis, in Adults (OP0595-5)

**sponsor of the trial:** Meiji Seika Pharma Co. Ltd.

**number of subjects in Estonia:** 74

**principal investigators and study locations:**

- Dr Andrei Uksov, Tartu University Hospital, L. Puusepa tn 8, 50406 Tartu, Estonia
- Dr Heino-Enn Arpo, Lääne-Tallinna Keskhaigla AS, Paldiski mnt 68, 10617 Tallinn, Estonia
- Dr Jaak Lind, Sihtasutus Ida-Viru Keskhaigla, Ilmajaama tn 12, 31025 Kohtla-Järve, Estonia
- Dr Marianne Laheäär, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Denis Uksov, Lõuna-Eesti Haigla AS, Meegomäe Village, 65526 Võru, 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