RAVIMIAMET

Artjom Vidal
PSI CRO OÜ
Narva mnt 90
10127 Tallinn
ESTONIA

22.02.2024 nr RKU-4/13

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 Spero Therapeutics Inc. on 17.10.2023 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 (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no SPR994-305 under the following conditions:

protocol no: SPR994-305 (Amendment 1, V2.0 dated June 06, 2023)

full title of the trial: A Phase 3, randomized, double-blind, double-dummy, multicenter, multinational study to assess the efficacy and safety of orally administered tebipenem pivoxil hydrobromide (TBP-PI-HBr) compared to intravenously (IV) administered imipenem-cilastatin in patients with complicated urinary tract infection (cUTI) or acute pyelonephritis (AP)

sponsor of the trial: Spero Therapeutics Inc.

number of subjects in Estonia: 126

starting date: February 2024

principal investigators and study locations:
- Dr Helen Ilumets, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Heino-Enn Arpo, Lääne-Tallinna Keskhaigla AS, Paldiski mnt 68, 10617 Tallinn, Estonia
- Dr Denis Uksov, Lõuna-Eesti Haigla AS, Meegomäe Village, 65526 Võru, Estonia
- Dr Andrei Uksov, Tartu University Hospital, L. Puusepa tn 8, 50406 Tartu, Estonia

- Dr Jaak Lind, Sihtasutus Ida-Viru Keskhaigla, Ilmajaama tn 12, 31025 Kohtla-Järve, Estonia
- Dr Kadi Kenk, Sihtasutus Pärnu Haigla, Ristiku tn 1, 80010 Pärnu, 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