



RAVIMIAMET

PSI CRO OÜ
Narva mnt 90
10127 Tallinn
ESTONIA

19.08.2024 nr RKU-4/58

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 Urogen Pharma Ltd. on 03.05.2024 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 BL013 under the following conditions:

protocol no: BL013 (Version 3.0, dated April 11, 2024)

full title of the trial: A Phase 3, Single-arm, Multicenter Study to Evaluate the Efficacy and Safety of UGN-103, a Novel Formulation of UGN-102, for the Treatment of Patients With Low Grade (LG) Nonmuscle Invasive Bladder Cancer (NMIBC) at Intermediate Risk (IR) of Recurrence (UTOPIA)

sponsor of the trial: Urogen Pharma Ltd.

number of subjects in Estonia: 7

starting date: October 2024

principal investigators and study locations:

- Dr Jaak Lind, Sihtasutus Ida-Viru Kesksaigla, Ilmajaama tn 12, 31025 Kohtla-Järve, Estonia
- Dr Tatjana Jõgis, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Roomet Ots, Tartu University Hospital, L. Puusepa tn 8, 50406 Tartu, Estonia
- Dr Heino-Enn Arpo, Lääne-Tallinna Kesksaigla AS, Paldiski mnt 68, 10617 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