



RAVIMIAMET

Urogen Pharma Ltd.
9 Ha-Ta'asiya
4365405 Ra'anana
ISRAEL

11.12.2024 nr RKU-4/91

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 03.10.2024 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 BL011 under the following conditions:

protocol no: BL011 (Version 5.0, dated February 28, 2024)

full title of the trial: A Phase 3, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of UGN-102 as Primary Chemoablative Therapy in Patients with Low Grade (LG) Non-Muscle-Invasive Bladder Cancer (NMIBC) at Intermediate Risk (IR) of Recurrence.

sponsor of the trial: Urogen Pharma Ltd.

number of subjects in Estonia: 14

principal investigators and study locations:

- 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 Keskhaigla AS, Paldiski mnt 68, 10617 Tallinn, Estonia
- Dr Toomas Tamm, East Tallinn Central Hospital, Ravi tn 18, 10138 Tallinn, Estonia
- Dr Jaak Lind, Sihtasutus Ida-Viru Keskhaigla, Ilmajaama tn 12, 31025 Kohtla-Järve, 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