



RAVIMIAMET

Sarah Liddle
AstraZeneca AB
Karlebyhus Byggnad 674
151 85 Sodertalje
SWEDEN

23.08.2024 nr RKU-4/63

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 on 25.07.2024 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 2 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no D9311C00001 under the following conditions:

protocol no: D9311C00001 (Version 6.0, dated January 24, 2023)

full title of the trial: A Randomised, Multicentre, Double-blind, Placebo-controlled, Phase III Study of First-line Carboplatin and Paclitaxel in Combination with Durvalumab, Followed by Maintenance Durvalumab with or without Olaparib in Patients with Newly Diagnosed Advanced or Recurrent Endometrial Cancer (DUO-E)

sponsor of the trial: AstraZeneca AB

number of subjects in Estonia: 4

principal investigators and study locations:

- Dr Elen Vettus, East Tallinn Central Hospital, Ravi tn 18, 10138 Tallinn, Estonia
- Dr Karin Grisan, Tartu University Hospital, L. Puusepa tn 1a, 50406 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