



RAVIMIAMET

Birgit Teppo
Optimapharm Estonia OÜ
Tiigi 78-308
50410 Tartu
EESTI

14.10.2024 nr RKU-4/79

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 Jazz Pharmaceuticals Ireland Limited on 03.09.2024 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 ZWI-ZW25-301 under the following conditions:

protocol no: ZWI-ZW25-301 (Version 4.0, dated January 26, 2024)

full title of the trial: A Randomized, Multicenter, Phase 3 Study of Zanidatamab in Combination with Chemotherapy with or without Tislelizumab in Subjects with HER2-positive Unresectable Locally Advanced or Metastatic Gastroesophageal Adenocarcinoma (GEA)

sponsor of the trial: Jazz Pharmaceuticals Ireland Limited

number of subjects in Estonia: 1

principal investigators and study locations:

- Dr Vivian Esko, East Tallinn Central Hospital, Ravi tn 18, 10138 Tallinn, Estonia
- Dr Niina Kippasto, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 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