



RAVIMIAMET

Christina Watanabe
Arena Pharmaceuticals Inc.
66 Hudson Boulevard East
10001-2189 New York
UNITED STATES

27.09.2024 nr RKU-4/77

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 Arena Pharmaceuticals Inc. on 30.08.2024 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 C5041012(APD334-303) under the following conditions:

protocol no: C5041012(APD334-303) (Version 4, dated February 20, 2023)

full title of the trial: C5041012 (APD334-303) - An Open-Label Extension Study of Etrasimod in Subjects with Moderately to Severely Active Ulcerative Colitis

sponsor of the trial: Arena Pharmaceuticals Inc.

number of subjects in Estonia: 9

principal investigators and study locations:

- Dr Julia Borissova, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Anu Mäelt, Lääne-Tallinna Keskhaigla AS, Paldiski mnt 68, 10617 Tallinn, Estonia
- Dr Jaak Tälli, Innomedica OÜ, Narva mnt 7, 10117 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