



RAVIMIAMET

Luigi Longo

Cosmo Technologies Limited

Riverside Two, 43-49 Sir John Rogerson's Quay

D02 KV60 Dublin

IRELAND

12.02.2024 nr RKU-4/8

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 Cosmo Technologies Limited on 22.08.2023 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 CB-01-35/01 under the following conditions:

protocol no: CB-01-35/01 (Version 2.0, dated November 17, 2023)

full title of the trial: Randomised, placebo-controlled Phase II proof of concept study of efficacy and safety of a novel rifamycin SV in situ gelling rectal solution administered by enema to patients with mild to moderate left-sided ulcerative colitis

sponsor of the trial: Cosmo Technologies Limited

number of subjects in Estonia: 6

starting date: February 2024

principal investigators and study locations:

- Dr Karin Kull, Tartu University Hospital, L. Puusepa tn 8, 50406 Tartu, Estonia
- Dr Vadim Brjalin, West Tallinn Central Hospital, 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