



RAVIMIAMET

Olga Koovit
IQVIA RDS Estonia OÜ
Narva mnt 3
51009 Tartu
ESTONIA

31.05.2024 nr RKU-4/36

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 Sun Pharmaceutical Industries Limited on 17.04.2024 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 TILD-19-07 under the following conditions:

protocol no: TILD-19-07 (Version Amendment 2, dated May 11, 2023)

full title of the trial: A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Demonstrate the Efficacy and Safety of Tildrakizumab in Anti-TNF Experienced Subjects with Active Psoriatic Arthritis I (INSPIRE 1)

sponsor of the trial: Sun Pharmaceutical Industries Limited

number of subjects in Estonia: 25

principal investigators and study locations:

- Dr Raili Müller, MediTrials OÜ, Mõisavahe tn 34c, 50708 Tartu, Estonia
- Dr Sandra Meisalu, Innomedica OÜ, Narva mnt 7, 10117 Tallinn, Estonia
- Dr Airi Põder, Kliiniliste Uuringute Keskus OÜ, Sõbra tn 54/1, 50106 Tartu, Estonia
- Dr Eevi Pärsik, 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