RAVIMIAMET

Artjom Vidal
PSI CRO OÜ
Narva mnt 90
10127 Tallinn
ESTONIA

14.10.2024 nr RKU-4/80

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 13.09.2024 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99^1 (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 § 99^6 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 SCD-044-19-16 under the following conditions:

protocol no: SCD-044-19-16 (Version 3.0, dated April 10, 2023)

full title of the trial: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO ASSESS THE EFFICACY AND SAFETY OF SCD-044 IN THE TREATMENT OF MODERATE TO SEVERE ATOPIC DERMATITIS

sponsor of the trial: Sun Pharmaceutical Industries Limited

number of subjects in Estonia: 4

principal investigators and study locations:

- Dr Airi Põder, Kliiniliste Uuringute Keskus OÜ, Sõbra tn 54/1, 50106 Tartu, 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