



RAVIMIAMET

Patrick Maury
Sanofi-Aventis Recherche & Développement
1 Avenue Pierre Brossolette
91380 Chilly Mazarin
FRANCE

30.04.2024 nr RKU-4/28

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 Sanofi-Aventis Recherche & Développement on 8.01.2024 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 2 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no LTS18133 under the following conditions:

protocol no: LTS18133 (Version 1, dated 29 March 2024)

full title of the trial: A double-blinded extension study to evaluate the long-term safety and tolerability of itepekimab in patients with chronic obstructive pulmonary disease (COPD) who participated in either EFC16750 or EFC16819 clinical studies

sponsor of the trial: Sanofi-Aventis Recherche & Développement

number of subjects in Estonia: 5

starting date: April 2024

principal investigators and study locations:

- Dr Rain Jõgi – Tartu University Hospital, L. Puusepa 1a, 50406 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