



RAVIMIAMET

Patrick Maury  
Sanofi-Aventis Recherche & Developpement  
82 Avenue Raspail  
94250 Gentilly  
FRANCE

23.08.2024 nr RKU-4/60

## 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 & Developpement on 17.07.2024 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99<sup>1</sup> (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<sup>6</sup> 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 EFC16819 under the following conditions:

**protocol no:** EFC16819 (Version 2, dated September 26, 2023)

**full title of the trial:** Randomized, double-blind, placebo-controlled, parallel-group Phase 3 study to evaluate the efficacy, safety, and tolerability of SAR440340/REGN3500/itepekimab (anti-IL-33 mAb) in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD)

**sponsor of the trial:** Sanofi-Aventis Recherche & Developpement

**number of subjects in Estonia:** 1

**principal investigators and study locations:**

- Dr Rain Jõgi, Tartu University Hospital, L. Puusepa tn 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