RAVIMIAMET

Patrick Maury
Sanofi-Aventis Research & Development
1 Avenue Pierre Brossolette
91380 Chilly Mazarin
FRANCE

09.05.2024 nr RKU-4/29

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 Research & Development on 11.01.2024 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 2 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no LTS17043 under the following conditions:

protocol no: LTS17043 (Version 5, dated December 21, 2023)

full title of the trial: An interventional, Phase 3 extension study to investigate long-term safety and tolerability of tolebrutinib in participants with relapsing multiple sclerosis, primary progressive multiple sclerosis, or nonrelapsing secondary progressive multiple sclerosis

sponsor of the trial: Sanofi-Aventis Research & Development

number of subjects in Estonia: 19

starting date: May 2024

principal investigators and study locations:
- Dr Sulev Haldre, Tartu University Hospital, L. Puusepa tn 1a, 50406 Tartu, Estonia
- Dr Katrin Gross-Paju, Clinic4U OÜ, Kotka tn 12 C, 11315 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