



RAVIMIAMET

Alexander Kainz
Novartis Pharma AG
Lichtstrasse 35
4056 Basel
SWITZERLAND

23.07.2024 nr RKU-4/51

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 Novartis Pharma AG on 13.06.2024 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 COMB157G2399 under the following conditions:

protocol no: COMB157G2399 (Version 03, dated April 13, 2023)

full title of the trial: An open-label, single arm, multi-center extension study evaluating long-term safety, tolerability and effectiveness of ofatumumab in subjects with relapsing multiple sclerosis (RMS)

sponsor of the trial: Novartis Pharma AG

number of subjects in Estonia: 29

principal investigators and study locations:

- Dr Sulev Haldre, Tartu University Hospital, L. Puusepa tn 1a, 50406 Tartu, Estonia
- Dr Katrin Gross-Paju, Lääne-Tallinna Keskhaigla AS, Paldiski mnt 68, 10617 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