RAVIMIAMET

Alexander Kainz
Novartis Pharma AG
Roonstrasse 25 Gostenhof
90429 Nuremberg
GERMANY

15.07.2024 nr RKU-4/44

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 30.05.2024 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 CBAF312D2301 under the following conditions:

protocol no: CBAF312D2301 (Version 01, dated 17 July 2023)

full title of the trial: A 2-year randomized, 3-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in pediatric patients with multiple sclerosis followed by an open-label extension

sponsor of the trial: Novartis Pharma AG

number of subjects in Estonia: 3

principal investigators and study locations:

- 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)

Ott Laius
Deputy Director General
on duties of Director General