RAVIMIAMET

Clinical Trial Accountable
F. Hoffmann-La Roche AG
Grenzacherstrasse 124
CH-4070 Basel
GERMANY

12.02.2024 nr RKU-4/11

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 F. Hoffmann-La Roche AG on 20.12.2023 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 WN42086 under the following conditions:

protocol no: WN42086 (Version 5, dated September 27, 2023)

full title of the trial: A Phase III Multicenter, Randomized, Double-Blind, Double-Dummy Study to Evaluate Safety and Efficacy of Ocrelizumab in Comparison with Fingolimod in Children and Adolescents with Relapsing-Remitting Multiple Sclerosis

sponsor of the trial: F. Hoffmann-La Roche AG

number of subjects in Estonia: 4

principal investigators and study locations:
- Dr Katrin Gross-Paju, Clinic4U OÜ, Kotka Tn 12 C, 11315 Tallinn, Estonia
- Dr Anneli Kolk, Tartu University Hospital, N. Lunini 6, 51014 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