RAVIMIAMET

Femke Sanders
Immunic AG
Lochhamer Schlag 21, Lochham
82166 Graefelfing
GERMANY

07.10.2024 nr RKU-4/78

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 Immunic AG on 03.09.2024 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 P3-IMU-838-RMS-02 under the following conditions:

protocol no: P3-IMU-838-RMS-02 (Version 4.0_EU01_consolidated, dated 22 August 2024)

full title of the trial: P3-IMU-838-RMS-02 - A Multi-Center, Randomized, Double-Blinded Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of IMU-838 versus Placebo in Adults with Relapsing Multiple Sclerosis (ENSURE-2)

sponsor of the trial: Immunic AG

number of subjects in Estonia: 20

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)

Katrin Kiisk
Director General