RAVIMIAMET

Boris Reznichenko
Otsuka Pharmaceutical Development &
Commercialization Inc.
2440 Research Boulevard
20850-3238 Rockville
UNITED STATES

20.05.2024 nr RKU-4/31

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 Otsuka Pharmaceutical Development & Commercialization Inc. on 20.03.2024 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 20-AVP-786-306 under the following conditions:

protocol no: 20-AVP-786-306 (Version 3.9, dated June 13, 2023)

full title of the trial: A Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of AVP-786 (deudextromethorphan hydrobromide [d6-DM]/quinidine sulfate [Q]) for the treatment of agitation in patients with dementia of the Alzheimer's type

sponsor of the trial: Otsuka Pharmaceutical Development & Commercialization Inc.

number of subjects in Estonia: 13

principal investigators and study locations:
- Dr Katrin Gross-Paju, Clinic4U OÜ, Kotka Tn 12 C, 11315 Tallinn, Estonia
- Dr Ülla Linnamägi, Tartu University Hospital, L. Puusepa tn 8, 50406 Tartu, Estonia
- Dr Kairi Mägi, Marienthali Kliinik 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