RAVIMIAMET

ICON Clinical Research Limited
Maldugunu str. 4
LV-2167, Marupe
LATVIA

23.09.2024 nr RKU-4/73

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 Argenx on 31.05.2024 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 2 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no ARGX-113-2301 under the following conditions:

protocol no: ARGX-113-2301 (Version 3.0 (Amendment 1.0), dated February 16, 2024)

full title of the trial: A Phase 3, Randomized, Double-Masked, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Immunogenicity of Efgartigimod PH20 SC Administered by Prefilled Syringe in Adult Participants With Thyroid Eye Disease

sponsor of the trial: Argenx

number of subjects in Estonia: 5

starting date: October 2024

principal investigators and study locations:
- Dr Maire Lubi, Tartu University Hospital, L. Puusepa tn 1a, 50406 Tartu, Estonia
- Dr Liina Viitas, Liina Viitas OÜ, Veetorni 2-1, 80018 Pärnu, 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