RAVIMIAMET

Syneos Health Latvia SIA
Kr.Valdemara street 21-11
LV-1010 Riga
LATVIA

28.02.2025 nr RKU-4/5

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 Intercept Pharmaceuticals Inc. on 28.10.2024 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 977-311 under the following conditions:

protocol no: 977-311 (Version 1, dated January 25, 2024)

full title of the trial: A Phase 3, Open-Label, Long-Term Safety Extension Study Evaluating the Safety and Tolerability of the Fixed-Dose Combination of Obeticholic Acid and Bezafibrate in Subjects with Primary Biliary Cholangitis

sponsor of the trial: Intercept Pharmaceuticals Inc.

number of subjects in Estonia: 2

starting date: March 2025

principal investigators and study locations:
- Dr Riina Salupere, Tartu University Hospital, L. Puusepa tn 8, 50406 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