



RAVIMIAMET

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Syneos Health Latvia
Krisjana Valdemara Street 21-11
LV-1010, Riga
LATVIA

18.06.2024 nr RKU-4/40

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 02.05.2024 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99¹ (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 § 99⁶ 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 747-213 under the following conditions:

protocol no: 747-213 (Version 6, dated October 31, 2023)

full title of the trial: A Phase 2, Double-Blind, Randomized, Parallel Group Study Evaluating the Efficacy, Safety, and Tolerability of Obeticholic Acid Administered in Combination with Bezafibrate in Subjects with Primary Biliary Cholangitis Who Had an Inadequate Response or Who Were Unable to Tolerate Ursodeoxycholic Acid

sponsor of the trial: Intercept Pharmaceuticals Inc.

number of subjects in Estonia: 2

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