RAVIMIAMET

Tim Cripps
Travere Therapeutics Inc.
2nd floor, Pepper Canister House, 3 Mount Street Crescent
D02 WC63 Dublin
IRELAND

27.09.2024 nr RKU-4/75

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 Travere Therapeutics Inc. on 23.08.2024 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 021FSGS16010 under the following conditions:

protocol no: 021FSGS16010 (Version AM9, dated January 18, 2024)

full title of the trial: A Randomized, Multicenter, Double-blind, Parallel, Active-control Study of the Effects of Sparsentan, a Dual Endothelin Receptor and Angiotensin Receptor Blocker, on Renal Outcomes in Patients with Primary Focal Segmental Glomerulosclerosis (FSGS)

sponsor of the trial: Travere Therapeutics Inc.

number of subjects in Estonia: 1

principal investigators and study locations:
- Dr Kadri Lilienthal, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Eesti
- Dr Mai Rosenberg, Tartu University Hospital, L. Puusepa tn 8, 50406 Tartu, Eesti
- Dr Madis Ilmoja, Lääne-Tallinna Keskhaigla AS, Paldiski mnt 68, 10617 Tallinn, Eesti

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