



RAVIMIAMET

Diana Loigom
North Estonia Medical Centre Foundation
J. Sütiste Tee 19
13419 Tallinn
ESTONIA

27.03.2024 nr RKU-4/22

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 North Estonia Medical Centre Foundation on 20.11.2023 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 TALTEC JNJ-54767414 under the following conditions:

protocol no: TALTEC JNJ-54767414 (Version 2.0, dated February 23, 2024)

full title of the trial: TALTEC: A phase II study measuring MRD negativity after bispecific T-cell redirectors TALquetamab and TEclistamab consolidation as part of first line treatment in transplant eligible multiple myeloma patients

sponsor of the trial: North Estonia Medical Centre Foundation

number of subjects in Estonia: 7

starting date: April 2024

principal investigators and study locations:

- Dr Diana Loigom, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 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