



RAVIMIAMET

Ulf Hannelius
Diamyd Medical AB
P. O. Box 7349
103 90 Stockholm
SWEDEN

16.07.2024 nr RKU-4/45

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 Diamyd Medical AB on 29.05.2024 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 D/P3/21/7 under the following conditions:

protocol no: D/P3/21/7 (Version 6.0, dated January 19, 2024)

full title of the trial: A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter Trial to Evaluate the Efficacy and Safety of Diamyd® to Preserve Endogenous Beta Cell Function in Adolescents and Adults with Recently Diagnosed Type 1 Diabetes, Carrying the Genetic HLA DR3-DQ2 Haplotype

sponsor of the trial: Diamyd Medical AB

number of subjects in Estonia: 18

principal investigators and study locations:

- Dr Aleksandr Peet, Tartu University Hospital, L. Puusepa tn 1a, 50406 Tartu, Estonia
- Dr Maire Lubi, Tartu University Hospital, L. Puusepa tn 1a, 50406 Tartu, Estonia
- Dr Anu Ambos, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, 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)

Ott Laius
Deputy Director General
on duties of Director General