



RAVIMIAMET

Renske Benedictus
Prinses Maxima Centrum voor Kinderoncologie B.V.
Heidelberglaan 25
3584 CS Utrecht
NETHERLANDS

02.08.2024 nr RKU-4/56

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 Prinses Maxima Centrum voor Kinderoncologie B.V. on 17.05.2024 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 MH21CHI under the following conditions:

protocol no: MH21CHI (Version 2.2, dated October 20, 2023)

full title of the trial: CHIP-AML22 Master protocol: An open label complex clinical trial in newly diagnosed pediatric de novo AML patients – a study by the NOPHO-DB-SHIP consortium Master Protocol

sponsor of the trial: Prinses Maxima Centrum voor Kinderoncologie B.V.

number of subjects in Estonia: 11

starting date: August 2024

principal investigators and study locations:

- Dr Sirje Mikkil, Tartu University Hospital, L. Puusepa tn 8, 50406 Tartu, Estonia
- Dr Maarja Karu, Tallinn Children's Hospital, Tervise 28, 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