RAVIMIAMET

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

16.09.2024 nr RKU-4/71

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 25.06.2024 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 1 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no MH22CAQ under the following conditions:

protocol no: MH22CAQ (Version 1-4, dated October 31, 2023)

full title of the trial: A phase II, single arm, open label, study on the safety, efficacy, pharmacokinetics and pharmacodynamics of quizartinib in combination with chemotherapy and as single-agent after high dose therapy in newly diagnosed pediatric FLT3-ITD positive and NPM1 wild-type AML patients (A linked-trial of the CHIP-AML22/Master protocol by the NOPHO-DB-SHIP consortium)

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

number of subjects in Estonia: 2

starting date: September 2024

principal investigators and study locations:
- Dr Maarja Karu, Tallinn Children´s Hospital, Tervise 28, 13419 Tallinn, Estonia
- Dr Sirje Mikkel, 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