



RAVIMIAMET

Hartmut Doehner
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Albert-Einstein-Allee 29, Eselsberg
89081 Ulm
GERMANY

24.01.2025 nr RKU-4/2

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 Universitaetsklinikum Ulm AöR on 23.10.2024 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 AMLSG31-19 under the following conditions:

protocol no: AMLSG31-19 (Version 2.2, dated July 16, 2024)

full title of the trial: A Randomized, Placebo-Controlled Phase III Study of Induction and Consolidation Chemotherapy With Venetoclax in Adult Patients With Newly Diagnosed Acute Myeloid Leukemia or Myelodysplastic Syndrome With Excess Blasts-2

sponsor of the trial: Universitaetsklinikum Ulm AöR

number of subjects in Estonia: 60

starting date: January 2025

principal investigators and study locations:

- Dr Ain Kaare, Tartu University Hospital, L. Puusepa tn 8, 50406 Tartu, Estonia
- Dr Katrin Palk, 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