



RAVIMIAMET

M. Breems  
Haemato Oncology Foundation For Adults  
Netherlands (HOVON)  
Dr. Molewaterplein 40  
3015 GD Rotterdam  
NETHERLANDS

18.11.2024 nr RKU-4/88

## 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 Haemato Oncology Foundation For Adults Netherlands (HOVON) on 15.10.2024 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99<sup>1</sup> (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<sup>6</sup> 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 HO150 under the following conditions:

**protocol no:** HO150 (Version 7, dated February 14, 2024)

**full title of the trial:** HOVON 150 AML: A phase 3, multicenter, double-blind, randomized, placebo-controlled study of ivosidenib or enasidenib in combination with induction therapy and consolidation therapy followed by maintenance therapy in patients with newly diagnosed acute myeloid leukemia or myelodysplastic syndrome with excess blasts-2, with an IDH1 or IDH2 mutation, respectively, eligible for intensive chemotherapy.

**sponsor of the trial:** Haemato Oncology Foundation For Adults Netherlands (HOVON)

**number of subjects in Estonia:** 2

**principal investigators and study locations:**

- Dr Ain Kaare, 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