



RAVIMIAMET

Dominik Jost  
HMNC Holding GmbH  
Wilhelm-Wagenfeld-Strasse 20, Schwabing-Freimann 27.09.2024 nr RKU-4/74  
80807 München  
GERMANY

## 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 HMNC Holding GmbH on 22.08.2024 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 BH-200-03 under the following conditions:

**protocol no:** BH-200-03 (Version 3, dated August 19, 2024)

**full title of the trial:** A 14-week, multicentre, double-blind, randomised, placebo-controlled phase II study with an 8-week treatment period to assess the efficacy and tolerability of a fixed dose of BH-200 (250 mg BID) in outpatients with Major Depressive Disorder (MDD)

**sponsor of the trial:** HMNC Holding GmbH

**number of subjects in Estonia:** 16

**principal investigators and study locations:**

- Dr Hanna Sova, OÜ Jaanson and Lääne, L. Puusepa tn 3, 50406 Tartu, Estonia
- Dr Kairi Mägi, Marienthali Kliinik OÜ, Kotka tn 12, 11315 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