



RAVIMIAMET

Alexander Kainz  
Novartis Pharma AG  
Roonstrasse 25 Gostenhof  
90429 Nuremberg  
GERMANY

20.05.2024 nr RKU-4/33

## 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 Novartis Pharma AG on 18.04.2024 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 CLNA043A12202 under the following conditions:

**protocol no:** CLNA043A12202 (Version 01, dated November 29, 2021)

**full title of the trial:** A 5- year randomized, double-blind, placebo-controlled, multi-center study assessing the efficacy, safety, and tolerability of intra-articular regimens of LNA043 versus placebo in patients with symptomatic knee osteoarthritis (ONWARDS)

**sponsor of the trial:** Novartis Pharma AG

**number of subjects in Estonia:** 24

**principal investigators and study locations:**

- Dr Ivo Valter, Center for Clinical and Basic Research AS, J. Pärna tn 4, 10128 Tallinn, Estonia
- Dr Raili Müller, MediTrials OÜ, Mõisavahe tn 34c, 50708 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