REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Unofficial translation of 18.05.2026 Decision RKU4/7

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 Boehringer Ingelheim International GmbH on 21.01.2026 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 2 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no 1438-0012 under the following conditions:

protocol no:	1438-0012 (Version 1.1, dated 06.05.2026)
EU CT nr:	2025-520565-51-00
full title of the trial:	DAREON®-Lung-1: A Phase III multi-center, open-label, randomised trial of intravenous obrixtamig in combination with atezolizumab, carboplatin, and etoposide vs. atezolizumab, carboplatin, and etoposide as first-line treatment in patients with extensive-stage small cell lung cancer.
sponsor of the trial:	Boehringer Ingelheim International GmbH
number of subjects in Estonia:	6
starting date:	May 2026

principal investigators and study locations:
- Dr. Kersti Oselin, North Estonia Medical Centre Foundation, Sütiste tee 19, 13419 Tallinn, Estonia
- Dr. Jana Jaal, Tartu University Hospital, Puusepa 1a, 50406 Tartu, Estonia

According to § 71(1) and § 75 of the Administrative Procedure Act a challenge to this decision may be filed within 30 days as from notification of the decision. Where the recipient wishes to contest the decision in administrative court, he or she may in accordance with the Code of

Administrative Court Procedure § 7 subsection 1 and 46 subsection 1 file complaint against the decision to Tartu Administrative Court within 30 days as from notification of the decision.