REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Unofficial translation of 04.09.2026 Decision RKU4/23

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 Sanofi-Aventis Recherche & Developpement on 23.06.2026 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 EFC22965 under the following conditions:

protocol no:	EFC22965 (Version 2, dated 24.08.2026)
EU CT number:	2026-525913-30-00
full title of the trial:	A parallel group, Phase 3, randomized, open-label, 2-arm study to demonstrate the superiority of belumosudil versus best available therapy (BAT) in participants at least 12 years of age with chronic graft versus host disease (cGVHD) refractory to or recurrent after 2 to 5 prior lines of systemic therapy
sponsor of the trial:	Sanofi-Aventis Recherche & Developpement
number of subjects in Estonia:	3
starting date:	Oktober 2026

principal investigators and study locations:
- Dr. Julia Abubikirova, Tartu Ülikooli Kliinikum SA (Tartu University Hospital), L. Puusepa 8, 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.