REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Unofficial translation of 28.07.2026 Decision RKU4/19

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 Generate Biomedicines Inc., represented in these proceedings by Clinical Technology Centre (Ireland) Limited, on 03.06.2026 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 1 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no GB-0895-302 under the following conditions:

protocol no:	GB-0895-302 (Version EU-2, dated 14.05.2026)
EU CT number:	2025-524040-35-00
full title of the trial:	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of GB-0895 Adjunctive Therapy in Adults and Adolescents with Severe Uncontrolled Asthma
sponsor of the trial:	Generate Biomedicines Inc.
number of subjects in Estonia:	7
starting date:	July 2026

principal investigators and study locations:
- Dr. Airi Põder, Kliiniliste Uuringute Keskus OÜ, Sõbra 54/1, 50106 Tartu, Estonia
- Dr. Raili Müller, MediTrials OÜ, Mõisavahe 34c, 50708 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.