



RAVIMIAMET

Lionel Bascles  
Genzyme Corp.  
450 Water Street  
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UNITED STATES

19.07.2024 nr RKU-4/49

## 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 Genzyme Corp. on 14.06.2024 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 EFC16035 under the following conditions:

**protocol no:** EFC16035 (Version 13, dated November 20, 2023)

**full title of the trial:** A Phase 3, randomized, double-blind, efficacy and safety study comparing SAR442168 to placebo in participants with primary progressive multiple sclerosis (PERSEUS)

**sponsor of the trial:** Genzyme Corp.

**number of subjects in Estonia:** 7

**principal investigators and study locations:**

- Dr Katrin Gross-Paju, Clinic4U OÜ, Kotka tn 12C, 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)

Ott Laius  
Deputy Director General  
on duties of Director General