



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-2751576

European Medicines Agency decision

EMA/PE/0000290054

of 2 January 2026

on the acceptance of a modification of an agreed paediatric investigation plan for human polyclonal immunoglobulin G against thymocyte in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.



European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for human polyclonal immunoglobulin G against thymocyte in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision EMA/PE/0000182592 issued on 2 July 2025,

Having regard to the application submitted by Sab Biotherapeutics Inc. on 6 August 2025 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 November 2025, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for human polyclonal immunoglobulin G against thymocyte, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Sab Biotherapeutics Inc., 2100 East 54th Street North, Sioux Falls, SD - 57104-5509, United States.

¹ OJ L 378, 27.12.2006, p.1, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-2376157

Amsterdam, 14 November 2025

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA/PE/0000290054

Scope of the application

Active substance(s):

Human polyclonal immunoglobulin G against thymocyte

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of stage 3 type 1 diabetes mellitus

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Sab Biotherapeutics Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sab Biotherapeutics Inc. submitted to the European Medicines Agency on 6 August 2025 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision EMA/PE/0000182592 issued on 2 July 2025.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 15 September 2025.



Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of stage 3 type 1 diabetes mellitus

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- solution for infusion, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of stage 3 type 1 diabetes mellitus

2.1.1. Indication(s) targeted by the PIP

To delay the progression of new onset Stage 3 type 1 diabetes mellitus (T1D)

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 1 year to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for infusion

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Study 1 (09-CR-006-01) Toxicity, toxicokinetic, and immunologic study of SAB-142 administered via intravenous infusion to juvenile cynomolgus monkeys.
Clinical studies	Study 2 (SAB-142-201) Randomised, double-blind, placebo-controlled, multi-arm parallel dose finding study, to evaluate pharmacokinetics, pharmacodynamics, efficacy and safety of SAB-142 in paediatric patients from 5 years of age (and adults) with new onset of stage 3 type 1 diabetes mellitus and documented residual beta cell function.

	<p>Study 3 (SAB-142-301)</p> <p>Randomised, double-blind, placebo-controlled, parallel-arm study evaluating the efficacy and safety of SAB-142 for delaying the progression of type 1 diabetes in stage 3 paediatric patients from 5 years to less than 18 years of age (and adults) with new onset of type 1 diabetes and documented residual beta cell function</p> <p>Study 4 (SAB-142-401)</p> <p>Clinical study to evaluate the efficacy, safety, pharmacokinetics and pharmacodynamics of SAB-142 in paediatric participants from 1 year to less than 5 years of age with stage 3 type 1 diabetes and documented residual beta cell function.</p>
Modelling and simulation analyses	<p>Study 5</p> <p>Population pharmacokinetics (PopPK) and pharmacokinetic-pharmacodynamic (PKPD) model to evaluate the relationship of SAB-142 as a disease-modifying therapy for Stage 2 and early Stage 3 T1D and to optimise dose finding.</p> <p>Study 6 (95-CR-001-01)</p> <p>Exposure response study to characterise the safety of SAB-142 in the paediatric population in relation to lymphocytes counts and function.</p>
Other studies	Not applicable
Extrapolation plan	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2033
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.