

EMA/554228/2023

European Medicines Agency decision

P/0508/2023

of 29 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for respiratory syncytial virus (RSV) PreF3 recombinant fusion protein/AS01 (RSVPreF3 OA) (EMEA-002904-PIP01-20-M01) 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.

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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 P/0456/2021 issued on 29 October 2021,

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A. on 7 August 2023 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 10 November 2023, 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.

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

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for respiratory syncytial virus (RSV) PreF3 recombinant fusion protein/AS01 (RSVPreF3 OA), powder and suspension for suspension for injection, intramuscular use, 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 GlaxoSmithKline Biologicals S.A., 89 Rue de l'Institut, 1330 – Rixensart, Belgium.

EMA/PDCO/365470/2023
Amsterdam, 10 November 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002904-PIP01-20-M01

Scope of the application

Active substance(s):

Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein/AS01 (RSVPreF3 OA)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

Pharmaceutical form(s):

Powder and suspension for suspension for injection.

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Biologicals S.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Biologicals S.A. submitted to the European Medicines Agency on 7 August 2023 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 P/0456/2021 issued on 29 October 2021.

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

The procedure started on 11 September 2023.

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:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

The waiver applies to:

- infants and toddlers from birth to less than 2 years of age;
- powder and suspension for suspension for injection; intramuscular use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

2.1.1. Indication(s) targeted by the PIP

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder and suspension for suspension for injection

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Study 1 (RSV OA=ADJ-015s) Randomized-controlled, observer-blind study with age-de-escalation, dose-escalating step, to assess the non-inferiority of the immune response and safety of one dose of RSVPreF3 OA investigational vaccine in children and adolescents with chronic conditions at increased risk of Respiratory Syncytial Virus (RSV) lower respiratory tract disease. Study 2 (RSV OA=ADJ-016) Open-label study to assess the immunogenicity, reactogenicity and safety of RSVPreF3 OA investigational vaccine in immunocompromised

	children and adolescents at high risk of lower respiratory tract disease
Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By April 2028
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