EMA/174920/2020

European Medicines Agency decision

P/0146/2020

of 18 April 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for pneumococcal polysaccharides individually biotinylated and complexed with a carrier protein (recombinant fusion construct of rhizavidin and Streptococcus pneumoniae derived proteins), 24-valent (EMEA-002641-PIP01-19) 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 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Astellas Pharma Europe, B.V. on 11 July 2019 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 February 2020, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for pneumococcal polysaccharides individually biotinylated and complexed with a carrier protein (recombinant fusion construct of rhizavidin and Streptococcus pneumoniae derived proteins), 24-valent, suspension for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for pneumococcal polysaccharides individually biotinylated and complexed with a carrier protein (recombinant fusion construct of rhizavidin and Streptococcus pneumoniae derived proteins), 24-valent, suspension for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for pneumococcal polysaccharides individually biotinylated and complexed with a carrier protein (recombinant fusion construct of rhizavidin and Streptococcus pneumoniae derived proteins), 24-valent, suspension for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Astellas Pharma Europe, B.V., Sylviusweg 62, 2333BE – Leiden, The Netherlands.

EMA/PDCO/694325/2019
Amsterdam, 28 February 2020

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-002641-PIP01-19

Scope of the application

Active substance(s):

Pneumococcal polysaccharides individually biotinylated and complexed with a carrier protein (recombinant fusion construct of rhizavidin and Streptococcus pneumoniae derived proteins), 24-valent

Condition(s):

Prevention of disease caused by *Streptococcus pneumoniae*

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Astellas Pharma Europe, B.V.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Astellas Pharma Europe, B.V. submitted for agreement to the European Medicines Agency on 11 July 2019 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 20 August 2019.

Supplementary information was provided by the applicant on 21 November 2019. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

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

2. The measures and timelines of the agreed 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 annex 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 disease caused by *Streptococcus pneumoniae.*

The waiver applies to:

- the paediatric population from birth to less than 6 weeks of age;
- suspension for injection, intramuscular use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric investigation plan

2.1. Condition:

Prevention of disease caused by *Streptococcus pneumoniae.*

2.1.1. Indication(s) targeted by the PIP

Active immunisation for the prevention of invasive pneumococcal diseases (IPD) caused by *S. pneumoniae.*

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

From 6 weeks to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Suspension for injection.

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	5	**Study 1:** Double-blind, randomised, single-dose, dose-escalation study to evaluate the safety, tolerability, reactogenicity and immunogenicity of ASP3772 compared to 13-valent pneumococcal conjugate vaccine (PCV13) in healthy toddlers from 12 to 15 months of age who have received the routine series of pneumococcal conjugate vaccine as infants (3772-CL-2001)

Area	Number of measures	Description
		Study 2: Double-blind, randomised, multiple-dose, dose-escalation/finding study to evaluate the safety, tolerability and immunogenicity of ASP3772 compared to an active PCV comparator in healthy infants (3772-CL-2002) **Study 3:** Double-blind, randomised, active-controlled study to evaluate the immunogenicity, safety, tolerability and reactogenicity of ASP3772 compared to an active PCV comparator in healthy infants. **Study 4:** Double-blind, randomised, active-controlled, catch-up study to evaluate the immunogenicity, safety and tolerability of ASP3772 compared to an active PCV comparator in healthy infants, toddlers and children. **Study 5:** Double-blind, randomised, active-controlled study to evaluate the immunogenicity, safety and tolerability of ASP3772 compared to an active PCV comparator in children and adolescents from 6 to less than 18 years of age who are at high-risk for IPD.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	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 March 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes