EMA/303246/2020

European Medicines Agency decision

P/0235/2020

of 19 June 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for sodium alginate oligosaccharide (EMEA-002321-PIP01-17) 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 AlgiPharma AS on 9 September 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 30 April 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 sodium alginate oligosaccharide, inhalation powder, hard capsule, inhalation 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 sodium alginate oligosaccharide, inhalation powder, hard capsule, inhalation 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 sodium alginate oligosaccharide, inhalation powder, hard capsule, inhalation 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 AlgiPharma AS, Industriveien 33, N-1337 - Sandvika, Norway.

EMA/PDCO/76976/2020
Amsterdam, 30 April 2020

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

EMEA-002321-PIP01-17

Scope of the application

Active substance(s):

Sodium alginate oligosaccharide

Condition(s):

Treatment of cystic fibrosis

Pharmaceutical form(s):

Inhalation powder, hard capsule

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

AlgiPharma AS

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, AlgiPharma AS submitted for agreement to the European Medicines Agency on 9 September 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 15 October 2019.

Supplementary information was provided by the applicant on 27 January 2020. 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)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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:

Treatment of cystic fibrosis

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- inhalation powder, hard capsule, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

2. Paediatric investigation plan

2.1. Condition:

Treatment of cystic fibrosis

2.1.1. Indication(s) targeted by the PIP

Treatment of respiratory symptoms in patients with cystic fibrosis

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Inhalation powder, hard capsule

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	4	**Study 1** Double-blind, four-arm randomised and dose-finding (part 1) and two-arm randomised single dose (part 2), placebo controlled trial to evaluate safety and efficacy of sodium alginate oligosaccharide as add-on to best standard of care in the paediatric population from 12 to less than 18 years of age and adults with cystic fibrosis in terms of superiority of over placebo (SMR-3372 / ORDCF-204).

		Study 2 Double-blind, four-arm randomised, dose-finding, placebo controlled trial to evaluate safety and efficacy of sodium alginate oligosaccharide as add-on to best standard of care in the paediatric population from 6 to less than 12 years of age with cystic fibrosis (ORDCF-206). **Study 3** Double-blind, double-dummy, three-arm randomised controlled trial to evaluate safety and efficacy of sodium alginate oligosaccharide as add-on to best standard of care in the paediatric population from 12 to less than 18 years of age and adults with cystic fibrosis in terms of non-inferiority of sodium alginate oligosaccharide as compared to pulmozyme with respect to placebo (ORDCF-301). **Study 4** Double-blind, double-dummy, three-arm randomised controlled trial to evaluate safety and efficacy of sodium alginate oligosaccharide as add-on to best standard of care in the paediatric population from 6 to less than 12 years of age with cystic fibrosis in terms of non-inferiority of sodium alginate oligosaccharide as compared to pulmozyme with respect to placebo (ORDCF-302).
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 August 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes