EMA/170158/2019

European Medicines Agency decision

P/0102/2019

of 22 March 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for dihomo-γ-linolenic acid (DS107) (EMEA-002364-PIP02-18) 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

P/0102/2019

of 22 March 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for dihomo-γ-linolenic acid (DS107) (EMEA-002364-PIP02-18) 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 726/2004[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 DS Biopharma Ltd. on 22 May 2018 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 1 February 2019, 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 dihomo-γ-linolenic acid (DS107) cream, topical 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 dihomo-γ-linolenic acid (DS107) cream, topical 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 dihomo-γ-linolenic acid (DS107) cream, topical 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 DS Biopharma Ltd., Trintech Building, South County Business Park, D18 – Dublin, Ireland.

EMA/PDCO/822980/2018
London, 1 February 2019

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

EMEA-002364-PIP02-18

Scope of the application

Active substance(s):

Dihomo-γ-linolenic acid (DS107)

Condition(s):

Treatment of atopic dermatitis

Pharmaceutical form(s):

Cream

Route(s) of administration:

Topical use

Name/corporate name of the PIP applicant:

DS Biopharma Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, DS Biopharma Ltd. submitted for agreement to the European Medicines Agency on 22 May 2018 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 26 June 2018.

Supplementary information was provided by the applicant on 24 October 2018. The applicant proposed modifications to the paediatric investigation plan.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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, by a majority of 24 out of 30 votes:

   - 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 divergent position is appended to this opinion.

   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 atopic dermatitis

The waiver applies to:

- the paediatric population from birth to less than 1 month of age;
- cream, topical 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 atopic dermatitis

2.1.1. Indication(s) targeted by the PIP

Treatment of mild to moderate atopic dermatitis

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

From 1 month to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Cream

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	3	**Study 1** Double-blind, randomised, vehicle-controlled trial to evaluate safety, efficacy and steroid sparing effect of dihomo-γ-linolenic acid (DS107) cream compared to vehicle in children from 2 to less than 18 years of age with mild to moderate atopic dermatitis (DS107E-09 AD7).

		Study 2 Open-label, extension study to evaluate safety and efficacy of dihomo-γ-linolenic acid (DS107) cream in children from 2 to less than 18 years of age who complete Study 1 (DS107E-09 AD7). (DS107E-10 AD8). **Study 3** Double-blind, randomised, vehicle-controlled trial to evaluate safety, efficacy and steroid sparing effect of dihomo-γ-linolenic acid (DS107) cream compared to vehicle in children from 1 month to less than 2 years of age with mild to moderate atopic dermatitis (DS107E-11 AD9).
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 July 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes