EMA/132884/2020

# European Medicines Agency decision

P/0129/2020

of 15 April 2020

on the agreement of a paediatric investigation plan and on the granting of a waiver for dihomo-γ-linolenic acid (DS107) (EMEA-002364-PIP03-19) 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 DS Biopharma Ltd. on 23 April 2019 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting 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 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 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 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), age-appropriate oral liquid dosage form, capsule, soft, oral 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 waiver for dihomo-γ-linolenic acid (DS107), age-appropriate oral liquid dosage form, capsule, soft, oral 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***

This decision is addressed to DS Biopharma Ltd., Trintech Building, South County Business Park, Leopardstown, D18 - Dublin Ireland.

EMA/PDCO/688578/2019
Amsterdam, 28 February 2020

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

EMEA-002364-PIP03-19

## Scope of the application

**Active substance(s):**

Dihomo-γ-linolenic acid (DS107)

**Condition(s):**

Treatment of atopic dermatitis

**Pharmaceutical form(s):**

Age-appropriate oral liquid dosage form

Capsule, soft

**Route(s) of administration:**

Oral 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 23 April 2019 an application for a paediatric investigation plan for the above-mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 28 May 2019.

Supplementary information was provided by the applicant on 27 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 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 atopic dermatitis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 2 years of age;
- age-appropriate oral liquid dosage form, capsule, soft, oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

# 2. Paediatric investigation plan

## *2.1. Condition:*

Treatment of atopic dermatitis

### 2.1.1. Indication(s) targeted by the PIP

Treatment of moderate to severe atopic dermatitis in adults and children

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

From 2 to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Age-appropriate oral liquid dosage form

Capsule, soft

### 2.1.4. Measures

| Area | Number of measures | Description |
|---|---|---|
| Quality-related studies | 1 | **Study 1**<br>Development of an age-appropriate oral liquid dosage form for use in children from 2 to less than 12 years of age |
| Non-clinical studies | 0 | Not applicable. |

| Area | Number of measures | Description |
|---|---|---|
| Clinical studies | 3 | **Study 2**<br><br>Open-label, randomised, 4-period, 4-sequence, single-dose crossover trial to compare bioavailability of DS107 age-appropriate oral liquid dosage form and DS107 soft capsule (DS107G-10 HV2)<br><br>**Study 3**<br><br>Double-blind, randomised, placebo-controlled trial to evaluate safety, efficacy and PK of DS107 as add-on to emollients and topical corticosteroids (TCS) in children from 2 to less than 18 years of age with moderate to severe atopic dermatitis (DS107G-08 AD6)<br><br>**Study 4**<br><br>Open-label, extension study to evaluate long-term safety and efficacy of DS107 in children from 2 to less than 18 years of age (and adults) who complete study 2 (DS107G-09 AD7) |
| 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 January 2025 |
| Deferral for one or more measures contained in the paediatric investigation plan: | No |