EMA/434139/2021

European Medicines Agency decision

P/0336/2021

of 11 August 2021

on the acceptance of a modification of an agreed paediatric investigation plan for sirolimus (EMEA-001416-PIP01-12-M03) 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/0336/2021

of 11 August 2021

on the acceptance of a modification of an agreed paediatric investigation plan for sirolimus (EMEA-001416-PIP01-12-M03) 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 European Medicines Agency's decision P/0079/2014 issued on 2 April 2014, decision P/0064/2017 issued on 17 March 2017, and decision P/0197/2018 issued on 19 July 2018,

Having regard to the application submitted by Santen Incorporated on 15 March 2021 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 25 June 2021, 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for sirolimus, solution for injection, intravitreal use, including changes to the deferral, 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 Santen Incorporated, 6401 Hollis Street, Suite 125, CA 94608 – Emeryville, USA.

EMA/PDCO/214093/2021
Amsterdam, 25 June 2021

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001416-PIP01-12-M03

Scope of the application

Active substance(s):

Sirolimus

Condition(s):

Treatment of chronic non-infectious uveitis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravitreal use

Name/corporate name of the PIP applicant:

Santen Incorporated

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Santen Incorporated submitted to the European Medicines Agency on 15 March 2021 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/0079/2014 issued on 2 April 2014, decision P/0064/2017 issued on 17 March 2017, and decision P/0197/2018 issued on 19 July 2018.

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

The procedure started on 27 April 2021.

Scope of the modification

Some 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 and to the deferral in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member 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 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 chronic non-infectious uveitis

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- for solution for injection, intravitreal use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan

2.1. Condition

Treatment of chronic non-infectious uveitis

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye

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

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Number of studies	Description
Quality related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	1	Open-label, non-comparative, uncontrolled study assessing the safety of intravitreal injections of sirolimus for the treatment of active, chronic non-infectious uveitis of the posterior segment of the eye in children and adolescents from 6 years to less than 18 years of age.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By July 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes