EMA/131632/2016

European Medicines Agency decision

P/0082/2016

of 18 March 2016

on the agreement of a paediatric investigation plan and on the granting of a waiver for tetracaine (hydrochloride) / oxymetazoline (hydrochloride) (EMEA-001764-PIP03-15) 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 St. Renatus, LLC on 19 October 2015 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 29 January 2016, in accordance with Article 18 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 tetracaine (hydrochloride) / oxymetazoline (hydrochloride), nasal spray, solution, nasal 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 tetracaine (hydrochloride) / oxymetazoline (hydrochloride), nasal spray, solution, nasal 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 St. Renatus, LLC, 1000 Centre Avenue, 80526 - Fort Collins, United States.

Done at London, 18 March 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/40567/2016 Corr
London, 29 January 2016

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

EMEA-001764-PIP03-15

Scope of the application

Active substance(s):

Tetracaine (hydrochloride) / oxymetazoline (hydrochloride)

Condition(s):

Local anaesthesia

Pharmaceutical form(s):

Nasal spray, solution

Route(s) of administration:

Nasal use

Name/corporate name of the PIP applicant:

St. Renatus, LLC

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, St. Renatus, LLC submitted for agreement to the European Medicines Agency on 19 October 2015 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 30 November 2015.

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 18 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:

Local anaesthesia

The waiver applies to:

- the paediatric population from birth to less than 3 years of age;
- nasal spray solution, nasal 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:

Local anaesthesia

2.1.1. Indication(s) targeted by the PIP

Topical anaesthesia producing anaesthesia of the maxillary teeth after intranasal application

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

From 3 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Nasal spray solution

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** Open-label, randomized, dose-ranging study to determine the lowest effective dose and to assess the efficacy and safety of intranasally administered tetracaine (hydrochloride) / oxymetazoline (hydrochloride) for anesthetizing maxillary teeth in paediatric patients from 3 to less than 18 years of age.

Area	Number of measures	Description
		Study 2 Randomized, double-blind, placebo-controlled, study to demonstrate the efficacy and safety of intranasal tetracaine (hydrochloride) / oxymetazoline (hydrochloride) vs placebo for inducing pulpal anaesthesia in maxillary teeth in paediatric patients from 3 to less than 18 years of age. **Study 3** Open-label, single-dose pharmacokinetic (PK) study to characterize the PK of tetracaine, its metabolite PBBA, and oxymetazoline in healthy paediatric subjects from 3 to less than 18 years of age.
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 November 2013
Deferral for one or more measures contained in the paediatric investigation plan:	No