EMA/131427/2016

European Medicines Agency decision

P/0047/2016

of 3 March 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for rolapitant (EMEA-001768-PIP02-15) 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 TESARO UK Ltd on 8 June 2015 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 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 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 rolapitant, tablets, age-appropriate oral dosage form, 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 deferral for rolapitant, tablets, age-appropriate oral dosage form, 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

A waiver for rolapitant, tablets, age-appropriate oral dosage form, 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 4

This decision is addressed to TESARO UK Ltd, c/o Sisec Limited, 21 Holborn Viaduct, EC1A 2DY - London, United Kingdom

Done at London, 3 March 2016

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

EMA/PDCO/752247/2015
London, 29 January 2016

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

EMEA-001768-PIP02-15

Scope of the application

Active substance(s):

Rolapitant

Condition(s):

Prevention of nausea and vomiting

Pharmaceutical form(s):

Tablets

Age-appropriate oral dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

TESARO UK Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, TESARO UK Ltd submitted for agreement to the European Medicines Agency on 8 June 2015 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 14 July 2015.

Supplementary information was provided by the applicant on 6 November 2015. The applicant proposed modifications to the paediatric investigation plan and requested a waiver.

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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 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   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:

Prevention of nausea and vomiting.

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- tablets, age-appropriate oral dosage form;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Prevention of nausea and vomiting.

2.1.1. Indication(s) targeted by the PIP

Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cisplatin-based cancer therapy and moderately emetogenic cancer therapy.

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Tablets, age-appropriate oral dosage form.

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate oral dosage form.
Non-clinical studies	1	**Study 2** Definitive juvenile toxicity study.

Area	Number of measures	Description
Clinical studies	3	**Study 3** Multicenter, open-label single dose study to evaluate the safety/tolerability and pharmacokinetic of rolapitant (part 1) followed by a randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of rolapitant compared to placebo as adjunct treatment to 5-HT3 receptor antagonists and dexamethasone in the prevention of nausea and vomiting (part 2) in paediatric patients from 12 to less than 18 years of age receiving highly emetogenic chemotherapy and moderately emetogenic chemotherapy treatment. **Study 4** Multicenter, open-label dose-ranging multi-cohort study to evaluate the safety/tolerability and pharmacokinetic of rolapitant in paediatric patients from 6 months to less than 12 years of age receiving highly emetogenic chemotherapy and moderately emetogenic chemotherapy treatment. **Study 5** Randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of rolapitant compared to placebo as adjunct treatment to 5-HT3 receptor antagonists and dexamethasone in the prevention of nausea and vomiting in paediatric patients from 6 months to less than 12 years of age receiving highly emetogenic chemotherapy and moderately emetogenic chemotherapy treatment. **Study 6** Single dose study comparing rolapitant tablets (reference) and age-appropriate oral liquid formulation (test) to evaluate the bioavailability between the two formulations in healthy adult subjects.
Extrapolation, modelling and simulation studies	1	**Study 7** Modelling and simulations study to evaluate the use and support dosing regimen of rolapitant in the prevention of nausea and vomiting in paediatric patients from 6 months to less than 18 years of age receiving highly emetogenic chemotherapy and moderately emetogenic chemotherapy treatment.
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 December 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes