EMA/124410/2020

European Medicines Agency decision

P/0107/2020

of 18 March 2020

on the acceptance of a modification of an agreed paediatric investigation plan for eluxadoline (Truberzi), (EMEA-001579-PIP01-13-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/0107/2020

of 18 March 2020

on the acceptance of a modification of an agreed paediatric investigation plan for eluxadoline (Truberzi), (EMEA-001579-PIP01-13-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/0021/2015 issued on 30 January 2015 and the decision P/0388/2017 issued on 19 December 2017,

Having regard to the application submitted by Allergan Pharmaceuticals International Limited on 25 October 2019 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 31 January 2020, 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.

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

[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 eluxadoline (Truberzi), film-coated tablet, age-appropriate oral liquid, oral use, 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 Allergan Pharmaceuticals International Limited, Clonshaugh Business and Technology Park, D17 E400 – Dublin, Ireland.

EMA/PDCO/616182/2019
Amsterdam, 31 January 2020

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

EMEA-001579-PIP01-13-M03

Scope of the application

Active substance(s):

Eluxadoline

Invented name:

Truberzi

Authorised indication(s):

See Annex II

Condition(s):

Treatment of diarrhoea-predominant irritable bowel syndrome

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral liquid

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Allergan Pharmaceuticals International Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Allergan Pharmaceuticals International Limited submitted to the European Medicines Agency on 25 October 2019 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/0021/2015 issued on 30 January 2015 and the decision P/0388/2017 issued on 19 December 2017.

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

The procedure started on 3 December 2019.

Scope of the modification

Some measures and 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 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 annexes 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 diarrhoea-predominant irritable bowel syndrome

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- film-coated tablet, age-appropriate oral liquid; 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 diarrhoea-predominant irritable bowel syndrome

2.1.1. Indication(s) targeted by the PIP

Treatment of diarrhoea-predominant irritable bowel syndrome

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet, age-appropriate oral liquid

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 5** Development of an age-appropriate oral liquid dosage form
Non-clinical studies	0	Not applicable
Clinical studies	3	**Study 1 (deleted during procedure EMEA-001579-PIP01-13-M02)** **Study 2** Double-blind, placebo-controlled study to evaluate safety and efficacy of Eluxadoline in children and adolescents 6 to less than 18 years with diarrhoea-predominant irritable bowel syndrome (IBS-d)

		Study 3 (added during procedure EMEA-001579-PIP01-13-M02) Randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study to evaluate dose-response, efficacy and safety of Eluxadoline in paediatric patients (age 12 - <18 years) with irritable bowel syndrome with diarrhoea (IBS-d) **Study 4 (added during procedure EMEA-001579-PIP01-13-M02)** Randomized, double-blind, placebo-controlled, sequential, ascending, multidose study, to evaluate dose-response, efficacy and safety of Eluxadoline in paediatric patients (age 6 - <12 years) with irritable bowel syndrome with diarrhoea (IBS-d)
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:	Yes
Date of completion of the paediatric investigation plan:	By August 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of IBS-D

Authorised indication(s):

- Truberzi is indicated in adults for the treatment of irritable bowel syndrome with diarrhoea (IBS-D).

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use