EMA/627335/2020

European Medicines Agency decision

P/0479/2020

of 1 December 2020

on the acceptance of a modification of an agreed paediatric investigation plan for teduglutide (Revestive) (EMEA-000482-PIP01-08-M06) 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 European Medicines Agency's decision P/238/2010 issued on 12 November 2010, the decision P/0236/2013 issued on 24 September 2013, the decision P/0137/2015 issued on 26 June 2015, the decision P/0245/2015 issued on 30 October 2015 and the decision P/0351/2017 issued on 1 December 2017, the decision P/0410/2019 issued on 6 December 2019,

Having regard to the application submitted by Shire Pharmaceuticals Ireland Limited on 13 July 2020 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 16 October 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 teduglutide (Revestive), powder and solvent for solution for injection, subcutaneous 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 Shire Pharmaceuticals Ireland Limited, Block 2, Miesian Plaza; 50-58, Baggot street, 2 Lower Dublin, Ireland.

EMA/PDCO/399310/2020
Amsterdam, 16 October 2020

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

EMEA-000482-PIP01-08-M06

Scope of the application

Active substance(s):

Teduglutide

Invented name:

Revestive

Condition(s):

Treatment of short bowel syndrome

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder and solvent for solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Shire Pharmaceuticals Ireland 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, Shire Pharmaceuticals Ireland Limited submitted to the European Medicines Agency on 13 July 2020 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/238/2010 issued on 12 November 2010, the decision P/0236/2013 issued on 24 September 2013, the decision P/0137/2015 issued on 26 June 2015, the decision

P/0245/2015 issued on 30 October 2015 and the decision P/0351/2017 issued on 1 December 2017 and the decision P/0410/2019 issued on 6 December 2019.

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

The procedure started on 18 August 2020.

Scope of the modification

Some measures 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 short bowel syndrome

The waiver applies to:

- neonates and infants from birth to less than 4 months of age;
- powder and solvent for solution for injection, subcutaneous use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition

Treatment of short bowel syndrome

2.1.1. Indication(s) targeted by the PIP

Treatment of short bowel syndrome

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

From 4 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder and solvent for solution for injection

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	1	**Study 1** Development of smaller strength or larger vial to avoid further dilution in children
Non-clinical studies	0	***Study 2*** *removed in procedure EMEA-000482-PIP01-08-M02* ***Study 3*** *removed in procedure EMEA-000482-PIP01-08-M02*
Clinical studies	3	**Study 4** 12-Week pharmacokinetic, safety and pharmacodynamic study of teduglutide in paediatric patients aged 1 to less than 18 years, with short bowel syndrome who are dependent on parenteral support (TED-C13-003)

		Study 5 *removed in procedure EMEA-000482-PIP01-08-M03* **Study 7** 24-week safety, efficacy and pharmacodynamic study of two doses of teduglutide in children less than 18 years of age (body weight greater than or equal to 10 kg) with short bowel syndrome who are dependent on parenteral support (TED-C14-006) **Study 8** 24-week safety, pharmacokinetic and pharmacodynamic study of teduglutide in infants aged from 4 months to less than 12 months with short bowel syndrome who are dependent on parenteral support (SHP633-301)
Extrapolation, modelling and simulation studies	1	**Study 6** Interpolation or extrapolation from adult or younger children data to paediatric subset 7 to less than 18 years of age

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 December 2020
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of short bowel syndrome

Authorised indication(s):

Revestive is indicated for the treatment of patients aged 1 year and above with Short Bowel Syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery.

Authorised pharmaceutical form(s):

Powder and solvent for solution for injection

Authorised route(s) of administration:

Subcutaneous use