EMA/564670/2013

European Medicines Agency decision

P/0236/2013

of 24 September 2013

on the acceptance of a modification of an agreed paediatric investigation plan for teduglutide (Revestive), (EMEA-000482-PIP01-08-M01) 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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on the acceptance of a modification of an agreed paediatric investigation plan for teduglutide (Revestive), (EMEA-000482-PIP01-08-M01) 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/238/2010 issued on 12 November 2010,

Having regard to the application submitted by Nycomed Danmark ApS on 17 May 2013 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 9 August 2013, 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 waiver.

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

Changes to the agreed paediatric investigation plan for teduglutide (Revestive), powder and solvent for solution for injection, subcutaneous use, including changes to the waiver, 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 Nycomed Danmark ApS, Langebjerg 1, DK-4000 Roskilde, Denmark.

Done at London, 24 September 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/323041/2013

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

EMEA-000482-PIP01-08-M01

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:

Nycomed Danmark ApS

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Nycomed Danmark ApS submitted to the European Medicines Agency on 17 May 2013 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.

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

The procedure started on 12 June 2013.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified and a waiver for a new paediatric subset has been added.

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 waiver 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 subsets of the paediatric population and condition 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.

London, 9 August 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

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;
- for powder 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 for solution for injection, subcutaneous use.

2.1.4. Studies

Area	Number of measures	Description
Quality	1	Development of smaller strength or larger vial to avoid further dilution in children
Non-clinical	2	Comparative receptor binding study Weaning from parenteral nutrition in piglets
Clinical	3	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 Weaning acceleration study after major intestinal resection 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

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By February 2017
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 adult patients with Short Bowel Syndrome. 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.