



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/398283/2015

European Medicines Agency decision

P/0137/2015

of 26 June 2015

on the acceptance of a modification of an agreed paediatric investigation plan for teduglutide (Revestive) (EMA-000482-PIP01-08-M02) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/238/2010 issued on 12 November 2010 and P/0236/2013 issued on 24 September 2013,

Having regard to the application submitted by Nycomed Danmark ApS on 27 February 2015 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 22 May 2015, 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 Nycomed Danmark ApS, Langebjerg 1, DK-4000 – Roskilde, Denmark.

Done at London, 26 June 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)



EUROPEAN MEDICINES AGENCY
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EMA/PDCO/148711/2015

London, 22 May 2015

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

EMA-000482-PIP01-08-M02

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 27 February 2015 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 and P/0236/2013 issued on 24 September 2013.

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

The procedure started on 24 March 2015.

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 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: 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. 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	2	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 Study 5: Weaning acceleration study after major intestinal resection
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

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