

EMA/201050/2013

European Medicines Agency decision

P/0106/2013

of 30 April 2013

on the acceptance of a modification of an agreed paediatric investigation plan for linaclotide (Constella), (EMA-000927-PIP01-10-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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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/110/2011 issued on 6 May 2011,

Having regard to the application submitted by Almirall S.A. on 17 December 2012 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 15 March 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.
- (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 linaclotide (Constella), capsule, hard, powder for oral solution, 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 Almirall S.A., 151 General Mitre, 08022 – Barcelona, Spain.

Done at London, 30 April 2013

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/820788/2012 **Corr.**

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000927-PIP01-10-M01

Scope of the application

Active substance(s):

Linaclotide

Invented name:

Constella

Condition(s):

Treatment of functional constipation

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Capsule, hard

Powder for oral solution

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Almirall S.A.

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Almirall S.A. submitted to the European Medicines Agency on 17 December 2012 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/110/2011 issued on 6 May 2011.

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

The procedure started on 16 January 2013.

Scope of the modification

Some timelines of the Paediatric Investigation Plan has 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(es) and appendix.

London, 15 March 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 functional constipation

The waiver applies to:

- The paediatric population from birth to less than 6 months of age;
- for capsule, hard and powder for oral solution for oral 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 functional constipation

2.1.1. Indication(s) targeted by the PIP

Treatment of functional constipation

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)

For capsule, hard and powder for oral solution, for oral use

2.1.4. Measures

Area	Number of measures	Description
Quality	1	Measure 1 Development of powder for oral solution.
Non-clinical	1	Measure 2 A 9-Week Oral Gavage Toxicity Study in Juvenile mice.
Clinical	7	Measure 3 Randomised, double-blind, placebo-controlled, dose-ranging study of Linaclotide in children, aged from 6 years to less than 18 years, with Functional Constipation Measure 4 Randomised, double-blind, placebo-controlled, ascending-dose, dose-ranging study of Linaclotide in children, aged from 3 years to less than 6 years, with Functional Constipation

Area	Number of measures	Description
		Measure 5 Randomised, double-blind, placebo-controlled, ascending-dose, dose-ranging study of Linaclotide in children, aged from 6 months to less than 3 years, with Functional Constipation. Measure 6 Randomised, double-blind, placebo-controlled, parallel-group, confirmatory study of Linaclotide in children aged from 3 years to less than 18 years with Functional Constipation. Measure 7 Randomised, double-blind, placebo-controlled, parallel-group, confirmatory study of Linaclotide in children aged from 6 months to less than 3 years with Functional Constipation. Measure 8 Open label, long-term safety study of Linaclotide in children aged from 3 years to less than 18 years with Functional Constipation. Measure 9 Open label, long-term safety study of Linaclotide in children aged from 6 months to less than 3 years with Functional Constipation.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	By August 2023.
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 moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults.

Authorised pharmaceutical formulation(s):

Capsule, hard

Authorised route(s) of administration:

Oral use