EMA/24831/2013

European Medicines Agency decision

P/0030/2013

of 26 February 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for proteinase, metallo- (synthetic nociceptin receptor-binding) 1290102-81-6 (AGN214868) (EMEA-001200-PIP01-11) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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 application submitted by Allergan Pharmaceuticals Ireland on 7 October 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 January 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation, and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a 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

A paediatric investigation plan for proteinase, metallo- (synthetic nociceptin receptor-binding) 1290102-81-6 (AGN214868), powder for solution for injection, intradermal use, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for proteinase, metallo- (synthetic nociceptin receptor-binding) 1290102-81-6 (AGN214868), powder for solution for injection, intradermal use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for proteinase, metallo- (synthetic nociceptin receptor-binding) 1290102-81-6 (AGN214868), powder for solution for injection, intradermal use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Allergan Pharmaceuticals Ireland, Marlow International, The Parkway, SL7 1YL - Marlow, Buckinghamshire, United Kingdom.

Done at London, 26 February 2013

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

EMA/PDCO/663449/2012

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-001200-PIP01-11

Scope of the application

Active substance(s):

Proteinase, metallo- (synthetic nociceptin receptor-binding) 1290102-81-6 (AGN214868)

Condition(s):

Treatment of postherpetic neuralgia

Treatment of overactive bladder

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Intradermal use

Intramuscular use

Name/corporate name of the PIP applicant:

Allergan Pharmaceuticals Ireland

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Allergan Pharmaceuticals Ireland submitted for agreement to the European Medicines Agency on 7 October 2011 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 16 November 2011.

Supplementary information was provided by the applicant on 3 October 2012. The applicant proposed modifications to the paediatric investigation plan.

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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation,
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population, and with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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.

London, 11 January 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 postherpetic neuralgia

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for powder for solution for injection for intradermal use and for intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition: treatment of overactive bladder

The waiver applies to:

- All subsets of the paediatric population from birth to less than 5 years of age;
- for powder for solution for injection for intradermal use and for intramuscular use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

The waiver applies to:

- Children from 5 to less than 8 years of age;
- for powder for solution for injection for intradermal use and for intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: treatment of overactive bladder

2.1.1. Indication(s) targeted by the PIP

Treatment of overactive bladder.

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

From 8 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for solution for injection for intramuscular use.

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	**Study 1:** A multicentre, double-blind, parallel group study of the safety and activity of three doses of AGN-214868, in paediatric patients with overactive bladder (OAB) and urinary incontinence.

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 March 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes