EMA/337481/2010

European Medicines Agency decision

P/89/2010

of 1 June 2010

on the agreement of a paediatric investigation plan and on the granting of a waiver for solifenacin succinate (Vesicare and associated names) (EMEA-000573-PIP01-09) 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 application submitted by Astellas Pharma Europe B.V. on 20 March 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 April 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, 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 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 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 solifenacin succinate (Vesicare and associated names), oral suspension, film-coated tablet, oral 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 waiver for solifenacin succinate (Vesicare and associated names), oral suspension, film-coated tablet, oral 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

This decision is addressed to Astellas Pharma Europe B.V., Elisabethhof 19, 2353 EW – Leiderdorp, The Netherlands.

Done at London, 1 June 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

EMA/337481/2010

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

EMEA-000573-PIP01-09

Scope of the application

Active substance(s):

Solifenacin succinate

Invented name:

Vesicare and associated names

Condition(s):

Idiopathic overactive bladder

Neurogenic detrusor overactivity

Pharmaceutical form(s):

Oral suspension

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Astellas Pharma Europe B.V.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Astellas Pharma Europe B.V. submitted for agreement to the European Medicines Agency on 20 March 2009 an application for a

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paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 30 April 2009.

Supplementary information was provided by the applicant on 1 February 2010.

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 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)(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 do 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(es) and appendix.

London, 16 April 2010

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

Annex I

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

1. Condition(s)

Idiopathic overactive bladder

Neurogenic detrusor overactivity

2. Waiver

2.1. Condition

Idiopathic overactive bladder

The waiver applies to:

- The paediatric population from birth to less than 5 years of age.
- for oral suspension, oral use
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

The waiver applies to:

- The paediatric population from birth to less than 18 years of age.
- for film-coated tablet, oral use
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2.2. Condition

Neurogenic detrusor overactivity

The waiver applies to:

- The paediatric population from birth to less than 6 months of age.
- for oral suspension, oral use
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

The waiver applies to:

- The paediatric population from birth to less 18 years of age.
- for film-coated tablet, oral use
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Idiopathic overactive bladder

3.1.1. Indication targeted by the PIP

Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome

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

From 5 years to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Oral suspension

3.1.4. Studies

Area	**Number of studies**	**Description**
Quality	1	*Study 1:* Development of an oral liquid age-appropriate formulation.
Non-clinical	0	Not applicable.
Clinical	3	*Study 4:* Open-label, multicentre, single ascending dose study to evaluate pharmacokinetics, safety and tolerability of solifenacin succinate suspension in children from 5 to less than 18 years of age with overactive bladder. *Study 5:* Double blind, randomised, multicentre, placebo controlled sequential dose titration study to assess efficacy, safety and population PK of solifenacin suspension in children from 5 to less than 18 years of age with overactive bladder. *Study 6:* Open-label, multicentre, sequential dose titration study to assess safety and efficacy of solifenacin succinate suspension in children from 5 to less than 18 years of age with overactive bladder from the safety/efficacy study (study 5).

3.2. Condition to be investigated

Neurogenic detrusor overactivity

3.2.1. Indication targeted by the PIP

Treatment of detrusor overactivity in children with neurogenic bladder dysfunction

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

From 6 months to less than 18 years of age.

3.2.3. Pharmaceutical form(s)

Oral suspension

3.2.4. Studies

Area	Number of studies	Description
Quality	1	*Study 1* (Same study as for condition idiopathic overactive bladder): Development of an oral liquid age-appropriate formulation.
Non-clinical	2	*Study 2:* 11-day dose range finding juvenile toxicity study in mice. *Study 3:* 12-week oral dose toxicity study in juvenile mice.
Clinical	3	*Study 4* (Same study as for condition idiopathic overactive bladder): Open-label, multicentre, single ascending dose study to evaluate pharmacokinetics, safety and tolerability of solifenacin succinate suspension in children from 5 to less than 18 years of age with overactive bladder. *Study 7:* Open label, baseline-controlled, multicentre, sequential dose titration study to assess PK, efficacy and safety of solifenacin succinate suspension in children from 5 to less than 18 years of age with neurogenic detrusor overactivity. *Study 8:* Open label, baseline-controlled, multicentre, sequential dose titration study to assess PK, efficacy and safety of solifenacin succinate suspension in children from 6 months to less than 5 years of age with neurogenic detrusor overactivity.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	December 2014
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Invented name **Name**	**Strength**	**Pharmaceutical form**	**Route of administration**
Vesicare and associated names	5 mg	Film-coated tablet	Oral use
Vesicare and associated names	10 mg	Film-coated tablet	Oral use