EMA/49423/2013

European Medicines Agency decision

P/0019/2013

of 1 February 2013

on the acceptance of a modification of an agreed paediatric investigation plan for solifenacin (succinate) (Vesicare and associated names), (EMEA-000573-PIP01-09-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 726/2004[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/89/2010 issued on 1 June 2010 and the decision P/314/2011 issued on 22 December 2011,

Having regard to the application submitted by Astellas Pharma Europe B.V. on 22 October 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 January 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 solifenacin (succinate) (Vesicare and associated names), oral suspension, film-coated tablet, 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 Astellas Pharma Europe B.V., Elisabethhof 19, 2353 EW – Leiderdorp, The Netherlands.

Done at London, 1 February 2013

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

EMA/49423/2013

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

EMEA-000573-PIP01-09-M02

Scope of the application

Active substance(s):

Solifenacin (succinate)

Invented name:

Vesicare and associated names

Condition(s):

Treatment of idiopathic overactive bladder

Treatment of neurogenic detrusor overactivity

Authorised indication(s):

See Annex II

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

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Astellas Pharma Europe B.V. submitted to the European Medicines Agency on 22 October 2012 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/89/2010 issued on 1 June 2010 and the decision P/314/2011 issued on 22 December 2011.

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

The procedure started on 14 November 2012.

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 Icelandic and the Norwegian Paediatric Committee members agree 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 annexes 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 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.

1.2. Condition: treatment of 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 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. Paediatric Investigation Plan

2.1. Condition: treatment of idiopathic overactive bladder

2.1.1. Indication(s) 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.

2.1.2. Pharmaceutical form(s)

From 5 years to less than 18 years of age.

2.1.3. 2.1.3. Pharmaceutical form(s)

Oral suspension.

2.1.4. 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 with overactive bladder (Long-term extension of Study 5 (905-CL-076)).

2.2. Condition: Treatment of neurogenic detrusor overactivity

2.2.1. Indication targeted by the PIP

Treatment of detrusor overactivity in children with neurogenic bladder dysfunction.

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

From 6 months to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Oral suspension.

2.2.4. Studies

Area	Number of studies	Description
Quality	1	*Study 1* (Same study as for treatment of 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 treatment of 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 long-term efficacy, safety, and pharmacokinetics 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.

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 December 2014.
Deferral for one or more measures contained in the paediatric investigation plan:	No.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of Overactive bladder

Authorised indication(s):

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

Authorised pharmaceutical formulation(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use