



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/508507/2015

European Medicines Agency decision

P/0170/2015

of 7 August 2015

on the acceptance of a modification of an agreed paediatric investigation plan for L-Cysteinyl-L-prolyl-L-alanyl-L-valyl-L-lysyl-L-arginyl-L-aspartyl-L-valyl-L-aspartyl-L-leucyl-L-phenylalanyl-L-leucyl-L-threonine, hydrochloride salt / L-Glutamyl-L-glutaminyl-L-valyl-L-alanyl-L-glutaminyl-L-tyrosyl-L-lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-L-asparaginyll-L-alanine, acetate salt / L-Lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-L-asparaginyll-L-alanyl-L-arginyl-L-iso-leucyl-L-leucyl-L-lysyl-L-asparaginyll-L-cysteinyl-L-valine, acetate salt / L-Arginyl-L-iso-leucyl-L-leucyl-L-lysyl-L-asparaginyll-L-cysteinyl-L-valyl-L-aspartyl-L-alanyl-L-lysyl-L-methionyl-L-threonyl-L-glutamyl-L-glutamyl-L-aspartyl-L-lysyl-L-glutamic acid, acetate salt / L-Lysyl-L-glutamyl-L-asparaginyll-L-alanyl-L-leucyl-L-seryl-L-leucyl-L-leucyl-L-aspartyl-L-lysyl-L-iso-leucyl-L-tyrosyl-L-threonyl-L-seryl-L-prolyl-L-leucine, acetate salt / L-Threonyl-L-alanyl-L-methionyl-L-lysyl-L-lysyl-L-iso-leucyl-L-glutaminyl-L-aspartyl-L-cysteinyl-L-tyrosyl-L-valyl-L-glutamyl-L-asparaginyll-glycyl-L-leucyl-L-iso-leucine, acetate salt / L-Seryl-L-arginyl-L-valyl-L-leucyl-L-aspartyl-glycyl-L-leucyl-L-valyl-L-methionyl-L-threonyl-L-threonyl-L-iso-leucyl-L-seryl-L-seryl-L-seryl-L-lysine, acetate salt (EMA-001054-PIP01-10-M03) 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/244/2011 issued on 7 October 2011, the decision P/0085/2012 issued on 21 May 2012 and the decision P/0199/2013 on 2 September 2013,

Having regard to the application submitted by Circassia Limited on 30 March 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 19 June 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 and to the deferral.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for L-Cysteinyl-L-prolyl-L-alanyl-L-valyl-L-lysyl-L-arginyl-L-aspartyl-L-valyl-L-aspartyl-L-leucyl-L-phenylalanyl-L-leucyl-L-threonine, hydrochloride salt / L-Glutamyl-L-glutaminyl-L-valyl-L-alanyl-L-glutaminyl-L-tyrosyl-L-lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-L-asparaginyl-L-alanine, acetate salt / L-Lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-L-asparaginyl-L-alanyl-L-arginyl-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginyl-L-cysteinyl-L-valine, acetate salt / L-Arginyl-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginyl-L-cysteinyl-L-valyl-L-aspartyl-L-alanyl-L-lysyl-L-methionyl-L-threonyl-L-glutamyl-L-glutamyl-L-aspartyl-L-lysyl-L-glutamic acid, acetate salt / L-Lysyl-L-glutamyl-L-asparaginyl-L-alanyl-L-leucyl-L-seryl-L-leucyl-L-leucyl-L-aspartyl-L-lysyl-L-isoleucyl-L-tyrosyl-L-threonyl-L-seryl-L-prolyl-L-leucine, acetate salt / L-Threonyl-L-alanyl-L-methionyl-L-lysyl-L-lysyl-L-isoleucyl-L-glutaminyl-L-aspartyl-L-cysteinyl-L-tyrosyl-L-valyl-L-glutamyl-L-asparaginyl-glycyl-L-leucyl-L-isoleucine, acetate salt / L-Seryl-L-arginyl-L-valyl-L-leucyl-L-aspartyl-glycyl-L-leucyl-L-valyl-L-methionyl-L-threonyl-L-threonyl-L-isoleucyl-L-seryl-L-seryl-L-seryl-L-lysine, acetate salt, powder for solution for injection, powder for solution for injection, including changes to the deferral, 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 Circassia Limited, Magdalen Centre, Robert Robertson Avenue, The Oxford Science Park, OX4 4GA – Oxford, United Kingdom.

Done at London, 7 August 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
SCIENCE MEDICINES HEALTH

EMA/PDCO/217810/2015 corr
London, 19 June 2015

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001054-PIP01-10-M03

Scope of the application

Active substance(s):

L-Cysteiny-L-prolyl-L-alanyl-L-valyl-L-lysyl-L-arginyl-L-aspartyl-L-valyl-L-aspartyl-L-leucyl-L-phenylalanyl-L-leucyl-L-threonine, hydrochloride salt / L-Glutamyl-L-glutaminyl-L-valyl-L-alanyl-L-glutaminyl-L-tyrosyl-L-lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-L-asparaginy-L-alanine, acetate salt / L-Lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-L-asparaginy-L-alanyl-L-arginyl-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginy-L-cysteiny-L-valine, acetate salt / L-Arginy-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginy-L-cysteiny-L-valyl-L-aspartyl-L-alanyl-L-lysyl-L-methionyl-L-threonyl-L-glutamyl-L-glutamyl-L-aspartyl-L-lysyl-L-glutamic acid, acetate salt / L-Lysyl-L-glutamyl-L-asparaginy-L-alanyl-L-leucyl-L-seryl-L-leucyl-L-leucyl-L-aspartyl-L-lysyl-L-isoleucyl-L-tyrosyl-L-threonyl-L-seryl-L-prolyl-L-leucine, acetate salt / L-Threonyl-L-alanyl-L-methionyl-L-lysyl-L-lysyl-L-isoleucyl-L-glutaminyl-L-aspartyl-L-cysteiny-L-tyrosyl-L-valyl-L-glutamyl-L-asparaginy-L-glycyl-L-leucyl-L-isoleucine, acetate salt / L-Seryl-L-arginyl-L-valyl-L-leucyl-L-aspartyl-L-glycyl-L-leucyl-L-valyl-L-methionyl-L-threonyl-L-threonyl-L-isoleucyl-L-seryl-L-seryl-L-seryl-L-lysine, acetate salt

Condition(s):

Treatment of perennial allergic rhinitis

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Intradermal use

Name / corporate name of the PIP applicant:

Circassia Limited



Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Circassia Limited submitted to the European Medicines Agency on 30 March 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/244/2011 issued on 7 October 2011, the decision P/0085/2012 issued on 21 May 2012 and the decision P/0199/2013 on 2 September 2013.

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

The procedure started on 21 April 2015.

Scope of the modification

Some measures and timelines 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 and to the deferral 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 perennial allergic rhinitis

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, intradermal 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 perennial allergic rhinitis

2.1.1. Indication targeted by the PIP

Treatment of cat allergen induced rhino-conjunctivitis in patients with clinically relevant symptoms

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

From 5 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for solution for injection

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	0	Not applicable
Non-clinical studies	1	Study 1 Juvenile toxicity study to evaluate organ system development and safety of Cat-PAD in juvenile rats
Clinical studies	3	Study 2 Double-blind, randomised, multi-centre, superiority, multiple-dose, placebo-controlled, parallel group study to evaluate efficacy and safety of Cat-PAD in cat allergic adolescents (and in adults)

		Study 3 Open label study with placebo run-in period to assess safety and tolerability of intradermal Cat-PAD administration in cat allergic children from 5 to less than 12 years Study 4 Double-blind, randomised, multi-centre, superiority, multiple-dose, placebo-controlled, parallel group study to evaluate efficacy and safety of Cat-PAD in cat allergic children from 5 to less than 12 years
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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 April 2019
Deferral for one or more studies contained in the paediatric investigation plan:	Yes