

EMA/500538/2010

European Medicines Agency decision

P/151/2010

of 16 August 2010

on the acceptance of a modification of an agreed paediatric investigation plan for zoledronic acid (Aclasta), (EMA-000057-PIP01-07-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 726/2004¹,

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/51/2008 issued on 20 July 2008,

Having regard to the application submitted by Novartis Europharm Limited on 1 April 2010 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 6 August 2010, 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) Regulation (EC) No 1901/2006, 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 zoledronic acid (Aclasta), solution for infusion, intravenous 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 Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom.

Done at London, 16 August 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/484451/2010

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan (after re-examination)

EMA-000057-PIP01-07-M02

Scope of the application

Active substance(s):

Zoledronic acid

Invented name:

Aclasta

Condition(s):

Paget's disease of the bone

Osteoporosis

Authorised indication(s): see Annex II

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 1 April 2010 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's



decision P/51/2008 of 20 July 2008. The application for modification proposed changes to the agreed paediatric investigation plan.

An Opinion was adopted by the Paediatric Committee on 11 June 2010 for the above mentioned product. Novartis Europharm Limited received the Paediatric Committee Opinion on 18 June 2010.

On 15 July 2010 Novartis Europharm Limited submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 16 July 2010.

A meeting with the Paediatric Committee took place on 4 August 2010.

Scope of the modification

Some timelines of the original Opinion have been modified.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

To revise its opinion and

- 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(s) agree(s) 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, 6 August 2010

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

Paget's disease of the bone

The waiver applies to:

- All paediatric subsets for 5mg/100ml solution for infusion for intravenous use.

1.2. Condition

Osteoporosis in post-menopausal women at an increased risk of fracture

The waiver applies to:

- All paediatric subsets for 5mg/100ml solution for infusion for intravenous use.

1.3. Condition

Osteoporosis in men at an increased risk of fracture

The waiver applies to:

- All paediatric subsets for 5mg/100ml solution for infusion for intravenous use.

1.4. Condition

Prevention of clinical fractures after a hip fracture in men and women

The waiver applies to:

- All paediatric subsets for 5mg/100ml solution for infusion for intravenous use.

1.5. Condition

Glucocorticoid-induced osteoporosis

The waiver applies to:

- Preterm newborn infants, term newborn infants, infants and toddlers and children less than 5 years of age for 5mg/100ml solution for infusion for intravenous use.

2. Paediatric Investigation Plan

2.1. Condition to be investigated

Glucocorticoid-induced osteoporosis

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

From 5 years to less than 18 years of age.

2.1.2. Pharmaceutical form(s)

5mg/100ml solution for infusion for intravenous use

2.1.3. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	1	Teratology study
Clinical	2	Global data collection and analysis on pregnancy outcome after bisphosphonate use Randomised, double-blind, placebo-controlled efficacy and safety study of intravenous zoledronic acid twice yearly compared to placebo in children with glucocorticoid-induced osteoporosis

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By July 2012
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1) Paget's disease of the bone

Authorised indications:

- Treatment of Paget's disease of the bone in adults.

2) Osteoporosis

Authorised indications:

Treatment of osteoporosis

- in post-menopausal women
- in men

at increased risk of fracture, including those with a recent low-trauma hip fracture.

Treatment of osteoporosis associated with long-term systemic glucocorticoid therapy

- in post-menopausal women
- in men

at increased risk of fracture.

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/05/308/001	Aclasta	5mg/100 ml	Solution for infusion	Intravenous use	bottle (plastic)	100 ml	1 bottle
EU/1/05/308/002	Aclasta	5mg/100 ml	Solution for infusion	Intravenous use	bottle (plastic)	100 ml	5 x 1 bottle (unit pack)