EMA/915429/2011

European Medicines Agency decision

P/289/2011

of 2 December 2011

on the acceptance of a modification of an agreed paediatric investigation plan for zoledronic acid (Aclasta) (EMEA-000057-PIP01-07-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 726/2004[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/51/2008 issued on 20 July 2008 and the decision P/151/2010 issued on 16 August 2010,

Having regard to the application submitted by Novartis Europharm Limited on 28 July 2011 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 14 October 2011, 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 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, RH12 5AB Horsham, Sussex, United Kingdom.

Done at London, 2 December 2011

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

EMA/PDCO/672731/2011

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

EMEA-000057-PIP01-07-M03

Scope of the application

Active substance(s):

Zoledronic acid

Invented name:

Aclasta

Condition(s):

Treatment of Paget's disease of the bone

Treatment of 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 28 July 2011 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 issued on 20 July 2008 and the decision P/151/2010 issued on 16 August 2010.

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

The procedure started on 16 August 2011.

A meeting with the Paediatric Committee took place on 12 October 2011.

Scope of the modification

The requirement for a non-clinical measure was removed.

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, 14 October 2011

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 Paget's disease of the bone

The waiver applies to:

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

1.2. Condition: Treatment of 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;
- for solution for infusion, intravenous use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of osteoporosis

2.1.1. Indication(s) targeted by the PIP

Treatment of glucocorticoid-induced osteoporosis.

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

From 5 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

5mg/100ml solution for infusion for intravenous use.

2.1.4. Studies

Area	**Number of studies**	**Description**
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	2	Study 1: Global data collection and analysis on pregnancy outcome after bisphosphonate use. Study 2: 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

Concerns on potential long term 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. Treatment of Paget's disease of the bone

   Authorised indications:

   Treatment of Paget’s disease of the bone in adults

2. Treatment of 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	5 mg/100 ml	Solution for infusion	Intravenous use	bottle (plastic)	100 ml	1 bottle
EU/1/05/308/002	Aclasta	5 mg/100 ml	Solution for infusion	Intravenous use	bottle (plastic)	100 ml	5 x 1 bottle (unit pack)