EMA/12235/2020

European Medicines Agency decision

P/0028/2020

of 17 January 2020

on the acceptance of a modification of an agreed paediatric investigation plan for zoledronic acid (Aclasta), (EMEA-000057-PIP01-07-M07) 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, the decision P/151/2010 issued on 16 August 2010, the decision P/289/2011 issued on 2 December 2011, the decision P/0169/2012 issued on 27 July 2012 and the decision P/0140/2013 issued on 3 July 2013,

Having regard to the application submitted by Novartis Europharm Limited on 6 September 2019 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 December 2019, 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, Vista Building Elm Park, Merrion Road, 4 - Dublin, Ireland.

EMA/PDCO/535471/2019
Amsterdam, 11 December 2019

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

EMEA-000057-PIP01-07-M07

Scope of the application

Active substance(s):

Zoledronic acid

Invented name:

Aclasta

Condition(s):

Treatment of osteoporosis

Treatment of Paget's disease of the bone

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 6 September 2019 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, the decision P/151/2010 issued on 16 August 2010, the decision P/289/2011 issued on 2 December 2011, the decision P/0169/2012 issued on 27 July 2012 and the decision P/0140/2013 issued on 3 July 2013.

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

The procedure started on 15 October 2019.

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 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 annexes 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 Paget's disease of the bone

The waiver applies to:

- all paediatric subsets;
- 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:

- the paediatric population of less than 5 years of age;
- 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 children at risk for 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. Measures

Area	Number of measures	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	2	Measure 1: Global data collection and analysis on pregnancy outcome after bisphosphonate use. Measure 2: Randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of intravenous zoledronic acid in children with symptoms of osteoporosis and an underlying condition treated systemically with glucocorticosteroids.

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 March 2018.
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 osteoporosis

Authorised indication(s):

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.

2. Treatment of Paget's disease of the bone

Authorised indication(s):

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

Authorised pharmaceutical form(s):

Solution for infusion

Authorised route(s) of administration:

Intravenous use