EMA/278983/2017

European Medicines Agency decision

P/0128/2017

of 12 May 2017

on the acceptance of a modification of an agreed paediatric investigation plan for cinacalcet (hydrochloride) (Mimpara), (EMEA-000078-PIP01-07-M08) 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/167/2009 issued on 14 August 2009, the decision P/166/2010 issued on 3 September 2010, the decision P/100/2011 issued on 11 April 2011, the decision P/0120/2012 issued on 3 July 2012, the decision P/0044/2014 issued on 7 March 2014, the decision P/0084/2015 issued on 8 May 2015 and the decision P/0008/2016 signed on 29 January 2016,

Having regard to the application submitted by Amgen Europe B.V. on 27 February 2017 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 21 April 2017, 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 cinacalcet (hydrochloride) (Mimpara), film-coated tablet, age-appropriate formulation, 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 Amgen Europe B.V., Minervum 7061, NL-4817 ZK – Breda, The Netherlands.

EMA/PDCO/180607/2017
London, 21 April 2017

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

EMEA-000078-PIP01-07-M08

Scope of the application

Active substance(s):

Cinacalcet (hydrochloride)

Invented name:

Mimpara

Condition(s):

Treatment of parathyroid carcinoma

Treatment of primary hyperparathyroidism

Treatment of secondary hyperparathyroidism in patients with end-stage renal disease

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Capsule, hard

Age-appropriate formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Amgen 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, Amgen Europe B.V. submitted to the European Medicines Agency on 27 February 2017 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/167/2009 issued on 14 August 2009, the decision P/166/2010 issued on 3 September 2010, the decision P/100/2011 issued on 11 April 2011, the decision P/0120/2012 issued on 3 July 2012, the decision P/0044/2014 issued on 7 March 2014, the decision P/0084/2015 issued on 8 May 2015 and the decision P/0008/2016 signed on 29 January 2016.

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

The procedure started on 21 March 2017.

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 parathyroid carcinoma

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for film-coated tablet, capsule, hard, and age-appropriate formulation, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

1.2. Condition

Treatment of primary hyperparathyroidism

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for film-coated tablet, capsule, hard, and age-appropriate formulation, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan

2.1. Condition to be investigated

Treatment of secondary hyperparathyroidism in patients with end-stage renal disease

2.1.1. Indication targeted by the PIP

Treatment of secondary hyperparathyroidism in patients with end-stage renal disease (ESRD) on maintenance dialysis therapy

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Capsule, hard

Age-appropriate formulation

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Development of age-appropriate paediatric formulation(s).
Non-clinical	2	**Study 1** Single dose, escalating PK study and 2-week toxicity study in juvenile dogs. **Study 2** 6-month oral gavage toxicity study in juvenile dogs.
Clinical	8	**Study 3:** deleted during procedure EMEA-000078-PIP01-07-M08 **Study 4** Open-label, non-randomized, single-dose PK/PD study of cinacalcet HCl in paediatric patients of less than 6 years, with chronic kidney disease receiving dialysis. (20090005). **Study 5** PK/PD modelling study to simulate repeated-dose administration in children from birth to less than 6 years. **Study 6** Randomized, double-blind, placebo-controlled study to assess the efficacy and safety of cinacalcet HCl in paediatric subjects (from 6 years to less than 18 years) with chronic kidney disease and secondary hyperparathyroidism, receiving dialysis. (20070208). **Study 7** Retrospective chart review to assess the use of cinacalcet for the treatment of secondary hyperparathyroidism in paediatric subjects age 0 to less than 6 years with chronic kidney disease on dialysis. **Study 8** PB/PK simulation in paediatric subjects less than 1 year of age. **Study 9** Open label study to assess the efficacy and safety of cinacalcet in children from 6 years to less than 18 years with chronic kidney disease and secondary hyperparathyroidism, receiving dialysis (20130356) **Study 10** Modelling/extrapolation study using adult and paediatric data. **Study 11** Bioequivalence study of the 5-mg capsule formulation to the film-coated tablet (in adults) (20160428).

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 December 2016
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 parathyroid carcinoma

Authorised indication:

- reduction of hypercalcaemia in patients with parathyroid carcinoma.

2. Treatment of primary hyperparathyroidism

Authorised indication:

- reduction of hypercalcaemia in patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated.

3. Treatment of secondary hyperparathyroidism in patients with end-stage renal disease

Authorised indications:

- treatment of secondary hyperparathyroidism (HPT) in patients with end-stage renal disease (ESRD) on maintenance dialysis therapy.

Authorised pharmaceutical form(s)

Film-coated tablet

Authorised route(s) of administration

Oral use