EMA/478292/2010

European Medicines Agency decision

P/166/2010

of 3 September 2010

on the acceptance of a modification of an agreed paediatric investigation plan for cinacalcet hydrochloride (Mimpara), (EMEA-000078-PIP01-07-M01) 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,

Having regard to the application submitted by Amgen Europe B.V on 26 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 16 July 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 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, capsule, 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, 4817-ZK Breda, The Netherlands.

Done at London, 3 September 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/416861/2010

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

EMEA-000078-PIP01-07-M01

Scope of the application

Active substance(s):

Cinacalcet hydrochloride

Invented name:

Mimpara

Condition(s):

Parathyroid carcinoma

Primary hyperparathyroidism

Secondary hyperparathyroidism in patients with end-stage renal disease

Pharmaceutical form(s):

Film-coated tablet

Capsule

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 26 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/167/2009 issued on 14 August 2009.

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

The procedure started on 20 May 2010.

Scope of the modification

Some measures and/or timelines of the original Opinion 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(s) agree(s) with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan 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, 16 July 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

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

1. Condition(s)

Parathyroid carcinoma

Primary hyperparathyroidism

Secondary hyperparathyroidism in patients with end-stage renal disease

1.1. Indication(s)

Authorised indications:

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

Reduction of hypercalcaemia in patients with:
- parathyroid carcinoma.
- 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.

2. Waiver

2.1. 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 cinacalcet film-coated tablet, capsule, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2.2. 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 cinacalcet film-coated tablet, capsule, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Secondary hyperparathyroidism in patients with end-stage renal disease

3.1.1. Indication targeted by the PIP

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

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

From birth to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

film-coated tablet, capsule, age-appropriate paediatric formulation

3.1.4. 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	5	• Study 3: Bioavailability/bioequivalence study of the 5-mg capsule formulation to the film-coated tablet (in adults) (20070293) • 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

4. 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 March 2015
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Package size
EU/1/04/292/001	Mimpara	30 mg	Film-coated tablet	Oral use	blister (Al/Aclar/PVAc/PVC)	14
EU/1/04/292/002	Mimpara	30 mg	Film-coated tablet	Oral use	blister (Al/Aclar/PVAc/PVC)	28
EU/1/04/292/003	Mimpara	30 mg	Film-coated tablet	Oral use	blister (Al/Aclar/PVAc/PVC)	84
EU/1/04/292/004	Mimpara	30 mg	Film-coated tablet	Oral use	bottle (HDPE)	30
EU/1/04/292/005	Mimpara	60 mg	Film-coated tablet	Oral use	blister (Al/Aclar/PVAc/PVC)	14
EU/1/04/292/006	Mimpara	60 mg	Film-coated tablet	Oral use	blister (Al/Aclar/PVAc/PVC)	28
EU/1/04/292/007	Mimpara	60 mg	Film-coated tablet	Oral use	blister (Al/Aclar/PVAc/PVC)	84
EU/1/04/292/008	Mimpara	60 mg	Film-coated tablet	Oral use	bottle (HDPE)	30
EU/1/04/292/009	Mimpara	90 mg	Film-coated tablet	Oral use	blister (Al/Aclar/PVAc/PVC)	14
EU/1/04/292/010	Mimpara	90 mg	Film-coated tablet	Oral use	blister (Al/Aclar/PVAc/PVC)	28
EU/1/04/292/011	Mimpara	90 mg	Film-coated tablet	Oral use	blister (Al/Aclar/PVAc/PVC)	84
EU/1/04/292/012	Mimpara	90 mg	Film-coated tablet	Oral use	bottle (HDPE)	30