EMA/301820/2013

European Medicines Agency decision

P/0125/2013

of 28 May 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral for lenvatinib (EMEA-001119-PIP02-12) 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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on the agreement of a paediatric investigation plan and on the granting of a deferral for lenvatinib (EMEA-001119-PIP02-12) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by Eisai Limited on 10 April 2012 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 April 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for lenvatinib, capsule, hard, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for lenvatinib, capsule, hard, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Eisai Europe Limited, Mosquito Way, AL10 9SN – Hatfield, United Kingdom.

Done at London, 28 May 2013

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

EMA/PDCO/75652/2013

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-001119-PIP02-12

Scope of the application

Active substance(s):

Lenvatinib

Condition(s):

Treatment of papillary thyroid cancer

Treatment of follicular thyroid cancer

Treatment of osteosarcoma

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Eisai Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Eisai Limited submitted for agreement to the European Medicines Agency on 10 April 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 15 May 2012.

Supplementary information was provided by the applicant on 16 January 2013. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

A meeting with the Paediatric Committee took place on 11 April 2013.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation.

   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 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 and appendix.

London, 12 April 2013

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

Not applicable

2. Paediatric Investigation Plan

2.1. Condition: treatment of follicular thyroid carcinoma and treatment of papillary thyroid carcinoma

2.1.1. Indication(s) targeted by the PIP

Treatment of children with ^{131}I-refractory follicular or papillary thyroid carcinoma

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)

Capsule, hard

2.1.4. Measures

Area	Number of measures	Description
Quality	1	Measure 1: Development of an oral suspension prepared from the hard capsule
Non-clinical	2	Measure 2: Toxicity study in juvenile rats Measure 3: Toxicity study in juvenile rats
Clinical	1	Measure 5: Open-label, multi-centre, non-controlled trial to evaluate pharmacokinetics, pharmacodynamics, tolerability and safety of lenvatinib in children from birth to less than 18 years of age with a relapsed or refractory solid malignant tumour and, in patients with osteosarcoma, an extension phase to evaluate lenvatinib in combination with cyclophosphamide and etoposide

2.2. Condition: treatment of osteosarcoma

2.2.1. Indication(s) targeted by the PIP

Treatment of children with a first relapse of osteosarcoma

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

From birth to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Capsule, hard

2.2.4. Measures

Area	Number of measures	Description
Quality	1	Measure 1: As for conditions treatment of follicular thyroid carcinoma and treatment of papillary thyroid carcinoma
Non-clinical	3	Measure 2: As for conditions treatment of follicular thyroid carcinoma and treatment of papillary thyroid carcinoma Measure 3: As for conditions treatment of follicular thyroid carcinoma and treatment of papillary thyroid carcinoma Measure 4: Pharmacology study of lenvatinib in combination with cyclophosphamide and etoposide in paediatric tumour models
Clinical	2	Measure 5: As for conditions treatment of follicular thyroid carcinoma and treatment of papillary thyroid carcinoma Measure 6: Multi-centre, randomized, controlled trial to evaluate the efficacy and safety of lenvatinib as add-on to cyclophosphamide combined with etoposide in children from 5 years to less than 18 years (and adults) with relapsed osteosarcoma

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes