EMA/478080/2010

European Medicines Agency decision

P/170/2010

of 3 September 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for bosutinib, (EMEA-000727-PIP01-09) 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 application submitted by Wyeth Europa Limited on 19 October 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 July 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and of its own motion in accordance with Article 12 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 and on the granting of a waiver.

(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.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[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 bosutinib, capsule and tablet, 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 bosutinib, capsule and tablet, 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

A product-specific waiver for bosutinib, capsule and tablet, 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 4

This decision is addressed to Wyeth Europa Limited, Huntercombe Lane South, Taplow, Maidenhead, Berkshire SL6 0PH, United-Kingdom.

Done at London, 3 September 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/422380/2010

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

EMEA-000727-PIP01-09

Scope of the application

Active substance(s):

Bosutinib

Condition(s):

Treatment of chronic myeloid leukaemia (CML)

Pharmaceutical form(s):

Capsule

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Wyeth Europa Limited

Basis for opinion

Pursuant to Article 16 (1) of Regulation (EC) No 1901/2006 as amended, Wyeth Europa Limited submitted for agreement to the European Medicines Agency on 19 October 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 19 November 2009.

Supplementary information was provided by the applicant on 23 April 2010.

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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,
   - to grant a waiver on its own motion for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with

     Articles 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   The Norwegian Paediatric Committee member(s) agree(s) 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(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)

Treatment of chronic myeloid leukaemia (CML)

2. Waiver

2.1. Condition

Treatment of chronic myeloid leukaemia (CML)

The waiver applies to:

- The paediatric population from birth to less than 10 years of age.
- For capsules and tablets for oral 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).

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Treatment of chronic myeloid leukaemia (CML)

3.1.1. Indication targeted by the PIP

- Treatment of chronic phase CML in children and adolescents (from 10 to less than 18 years of age);
- Treatment of chronic, accelerated or blast phase CML in children and adolescents with resistance or intolerance to prior therapy including imatinib.

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

From 10 to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

- Capsule 20 mg and 50 mg with age-appropriate size
- Tablet 100 mg and 500 mg with age-appropriate size

3.1.4. Studies

Area	Number of studies	Description
Quality		Study 1 Development of age appropriate formulation and strength.

Area	Number of studies	Description
Clinical	2	Study 2 Open-label, multicentre, uncontrolled, dose-finding study to evaluate the PK, safety, and activity bosutinib in paediatric patients from 10 to less than 18 years of age with Ph+ CML in chronic phase, who are resistant or intolerant to prior Tyrosine Kinase Inhibitor (TKI) therapy. Study 3 Bioequivalence study with bosutinib in adults with paediatric age-appropriate formulation.

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:	December 2016
Deferral for one or more studies contained in the paediatric investigation plan:	Yes