EMA/330478/2010

European Medicines Agency decision

P/86/2010

of 1 June 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the refusal of a waiver for cediranib maleate (EMEA-000477-PIP01-08) 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 AstraZeneca AB on 26 February 2009 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 16 April 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 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 refusal 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 refusing 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 cediranib maleate, 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 cediranib maleate, 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 waiver for cediranib maleate, 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 refused.

Article 4

This decision is addressed to AstraZeneca AB, Building 411A Floor 4, S-151 85 Södertälje, Sweden.

Done at London, 1 June 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/98975/2010

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

EMEA-000477-PIP01-08

Scope of the application

Active substance(s):

Cediranib maleate

Condition(s):

High-grade glioma

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted for agreement to the European Medicines Agency on 26 February 2009 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 2 April 2009.

Supplementary information was provided by the applicant on 5 February 2010.

A meeting with the Paediatric Committee took place on 15 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 refuse the granting of a waiver in accordance with Article 13 of said Regulation, for some of the subsets of the paediatric population and the above mentioned condition(s) as it does not meet the grounds detailed in Article 11(1) 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(es) and appendix.

London, 16 April 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

1. Condition(s)

High-grade glioma

2. Waiver

Not applicable

3. Paediatric Investigation Plan

3.1. Condition to be investigated

High-grade glioma

3.1.1. Indication targeted by the PIP

Treatment of newly-diagnosed high-grade glioma in paediatric patients from 1 year to less than 18 years of age, in combination with temozolomide (with or without radiation therapy)

Treatment of recurrent or progressive high-grade glioma in paediatric patients aged from 1 year to less than 18 years of age, in combination with temozolomide

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)

Tablet.

Presentations to include 5 mg strength.

3.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: Development of a 5 mg strength tablet that can be dispersed for oral use.
Non-clinical	0	Not applicable.
Clinical	3	Study 2: Open-label, multicentre, multiple dose trial to evaluate pharmacokinetics, safety and activity of cediranib in children from 2 years to less than 19 years age with refractory or recurrent solid tumours. Study 3: Open-label, multicentre, multiple dose trial to evaluate pharmacokinetics and safety of cediranib in children from 1 year to less than 18 years of age with refractory or recurrent solid tumours of the central nervous system Study 4: Double-blind, randomised, parallel-group, placebo-controlled add-on, multi-centre trial to evaluate pharmacokinetics, safety and

Area	Number of studies	Description
		efficacy of cediranib added to temozolomide in children from birth to less than 18 years with newly-diagnosed high-grade glioma, including a run-in period and an open-label stratum with children with first progression or first relapse of high-grade glioma

4. Follow-up, completion and deferral of pip

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	By December 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes