



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/174396/2011

European Medicines Agency decision P/66/2011

of 11 March 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for bevacizumab (Avastin) (EMA-000056-PIP03-10) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Roche Registration Ltd on 1 July 2010 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 18 February 2011, 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 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 bevacizumab (Avastin), concentrate for solution for infusion, intravenous 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 bevacizumab (Avastin), concentrate for solution for infusion, intravenous 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 bevacizumab (Avastin), concentrate for solution for infusion intravenous 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 Roche Registration Ltd, 6 Falcon Way, Shire Park, AL7 1TW, Welwyn Garden City, United Kingdom, Roche Registration Ltd.

Done at London, 11 March 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director

(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/49344/2011

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

EMA-000056-PIP03-10

Scope of the application

Active substance(s):

Bevacizumab

Invented name:

Avastin

Condition(s):

Treatment of high-grade glioma

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Roche Registration Ltd

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Roche Registration Ltd submitted for agreement to the European Medicines Agency on 1 July 2010 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 12 August 2010.

Supplementary information was provided by the applicant on 4 December 2010. The applicant proposed modifications to the paediatric investigation plan.

A meeting with the Paediatric Committee took place on 16 February 2011.

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 for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

The Icelandic and the Norwegian Paediatric Committee members do agree with the above-mentioned recommendation of the Paediatric Committee.

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, 18 February 2011

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

1.1. Condition: Treatment of high-grade glioma

The waiver applies to:

- the paediatric population from birth to less than 6 months,
- for the concentrate for solution for infusion for intravenous use,
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of high-grade glioma

2.1.1. Indication(s) targeted by the PIP

Treatment of newly-diagnosed high-grade glioma

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

From 6 months to less than 18 years.

2.1.3. Pharmaceutical form(s)

Concentrate for solution for infusion for intravenous use

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Study 1: Open-label, randomised, multi-centre trial to evaluate pharmacokinetics, safety and efficacy of bevacizumab as add-on to baseline therapy in children from 3 years to less than 18 years of age with newly-diagnosed supratentorial, non-brainstem high-grade glioma; including an exploratory single-arm, open-label, multi-centre trial to evaluate pharmacokinetics, safety and activity of bevacizumab added to best investigator's choice in children aged 6 months to less than 3 years with high-grade glioma following first-line chemo-surgical therapy

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2016

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

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of carcinoma of the colon or rectum.

Authorised indications:

Avastin (bevacizumab) in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of patients with metastatic carcinoma of the colon or rectum.

2. Treatment of breast cancer.

Authorised indications:

Avastin in combination with paclitaxel or docetaxel is indicated for first-line treatment of patients with metastatic breast cancer.

3. Treatment of non-small cell lung cancer.

Authorised indications:

Avastin, in addition to platinum-based chemotherapy, is indicated for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology.

4. Treatment of renal cell cancer.

Authorised indication:

Avastin in combination with interferon alfa-2a is indicated for first line treatment of patients with advanced and/or metastatic renal cell cancer.

EU number	(Invented) name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/04/300/001	Avastin	25 mg/ml	Concentrate for solution for infusion	Intravenous use	vial (glass)	4 ml	1 vial
EU/1/04/300/002	Avastin	25 mg/ml	Concentrate for solution for infusion	Intravenous use	vial (glass)	16 ml	1 vial