EMA/636944/2012

European Medicines Agency decision

P/0235/2012

of 22 October 2012

on the acceptance of a modification of an agreed paediatric investigation plan for bevacizumab (Avastin), (EMEA-000056-PIP03-10-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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on the acceptance of a modification of an agreed paediatric investigation plan for bevacizumab (Avastin), (EMEA-000056-PIP03-10-M01) 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 European Medicines Agency's decision P/66/2011 issued on 11 March 2011,

Having regard to the application submitted by Roche Registration Ltd. on 18 June 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 7 September 2012, 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 bevacizumab (Avastin), concentrate for solution for infusion, intravenous 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 Roche Registration Ltd., 6 Falcon Way, Shire Park, AL7 1TW - Welwyn Garden City, United Kingdom.

Done at London, 22 October 2012

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

EMA/636944/2012

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

EMEA-000056-PIP03-10-M01

Scope of the application

Active substance(s):

Bevacizumab

Invented name:

Avastin

Condition(s):

Treatment of high-grade glioma

Authorised indication(s):

See Annex II

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

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Roche Registration Ltd. submitted to the European Medicines Agency on 18 June 2012 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/66/2011 issued on 11 March 2011.

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

The procedure started on 11 July 2012.

Scope of the modification

Some measures of the Paediatric Investigation Plan 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 Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the 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, 7 September 2012

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

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2016
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**	**Pharma-ceutical form**	**Route of admini-stration**	**Pack-aging**	**Content (concent ration)**	**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