EMA/847881/2011

European Medicines Agency decision

P/269/2011

of 28 October 2011

on the acceptance of a modification of an agreed paediatric investigation plan for ombrabulin (EMEA-000800-PIP01-09-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 ombrabulin (EMEA-000800-PIP01-09-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/120/2011 issued on 7 June 2011,

Having regard to the application submitted by Sanofi-aventis recherche & developpement on 4 July 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 September 2011, 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 ombrabulin, 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 Sanofi-aventis recherche & developpement, 1 avenue Victor Basch, 91300 Massy, France.

Done at London, 28 October 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/645160/2011

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

EMEA-000800-PIP01-09-M01

Scope of the application

Active substance(s):

Ombrabulin

Condition(s):

Treatment of rhabdomyosarcoma

Treatment of non-rhabdomyosarcoma soft tissue sarcoma

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Sanofi-aventis recherche & developpement

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi-aventis recherche & developpement submitted to the European Medicines Agency on 4 July 2011 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/120/2011 issued on 7 June 2010.

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

The procedure started on 13 July 2011.

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Scope of the modification

A measure of the Paediatric Investigation Plan was 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 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, 9 September 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

Not applicable.

2. Paediatric Investigation Plan

2.1. Conditions: Treatment of rhabdomyosarcoma and treatment of non-rhabdomyosarcoma soft tissue sarcoma

2.1.1. Indication(s) targeted by the PIP

- Treatment of metastatic or locally advanced rhabdomyosarcoma soft tissue sarcoma;
- Treatment of relapsed / progressive non-rhabdomyosarcoma soft tissue sarcoma.

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)

Concentrate for solution for infusion.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	2	Study 1: Juvenile toxicity study. Study 2: Juvenile toxicokinetic study
Clinical	2	Study 3: Uncontrolled, non-randomized, open label dose-escalation trial to evaluate safety, pharmacokinetics and activity of ombrabulin and a combination of ombrabulin with vincristine and irinotecan in children with refractory or relapsed solid tumours. Study 4: Double-blind, randomized, placebo-controlled trial to evaluate the safety and efficacy of ombrabulin in combination with vincristine and irinotecan in children with rhabdomyosarcoma and non-rhabdomyosarcoma.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By Dec 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes