EMA/446651/2015

European Medicines Agency decision

P/0162/2015

of 10 July 2015

on the acceptance of a modification of an agreed paediatric investigation plan for ipilimumab (Yervoy), (EMEA-000117-PIP02-10-M06) 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 European Medicines Agency's decision P/128/2011 issued on 8 June 2011, the decision P/0265/2011 issued on 28 October 2011, the decision P/0116/2012 issued on 2 July 2012, and the decision P/0093/2014 issued on 7 April 2014,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 27 March 2015 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 19 June 2015, 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[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 ipilimumab (Yervoy), concentrate for solution for infusion, intravenous use, including changes to the deferral, 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 Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sand Road, UB8 1DH – Uxbridge, United Kingdom.

Done at London, 10 July 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/241215/2015
London, 19 June 2015

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

EMEA-000117-PIP02-10-M06

Scope of the application

Active substance(s):

Ipilimumab

Invented name:

Yervoy

Condition(s):

Treatment of melanoma

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:

Bristol-Myers Squibb Pharma EEIG

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, Bristol-Myers Squibb Pharma EEIG submitted to the European Medicines Agency on 27 March 2015 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/128/2011 issued on 8 June 2011, the decision P/0265/2011 issued on 28 October 2011, the decision P/0116/2012 issued on 2 July 2012, and the decision P/0093/2014 issued on 7 April 2014.

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

The procedure started on 21 April 2015.

Scope of the modification

Some measures and the timelines 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 and to the deferral in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees 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 annexes and appendix.

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 (PIP)

1. Waiver

Not applicable.

2. Paediatric Investigation Plan

2.1. *Condition:*

Treatment of melanoma.

2.1.1. Indication(s) targeted by the PIP

Treatment of pre-treated and naive patients with advanced metastatic melanoma.

Treatment of patients with melanoma (surgically resected) in the adjuvant setting.

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

From 12 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Concentrate for solution for infusion.

2.1.4. Measures

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	**Study 1** Intravenous study of pre- and postnatal development in cynomolgus monkeys with a 6-month postnatal evaluation.
Clinical	3	**Study 2** Open-label, dose escalation clinical trial of intravenously administered ipilimumab in children from 2 to less than 18 years (and in young adults to 21 years) with untreatable, refractory or relapsed solid malignant tumours. **Study 3** Open-label, multi-centre, single-arm clinical trial of intravenously administered ipilimumab in children aged 12 to less than 18 years with untreated or previously treated advanced/metastatic melanoma. **Study 4** Open-label randomized active-controlled study of adjuvant ipilimumab anti-CTLA4 therapy versus high-dose interferon

		α-2b in children aged 12 to less than 18 years (and adults) with resected high-risk melanoma.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

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 June 2018
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 melanoma

Authorised indication(s):

- Yervoy is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults.

Authorised pharmaceutical form(s)

Concentrate for solution for infusion

Authorised route(s) of administration

Intravenous use