EMA/186334/2014

European Medicines Agency decision

P/0092/2014

of 7 April 2014

on the acceptance of a modification of an agreed paediatric investigation plan for ipilimumab (Yervoy), (EMEA-000117-PIP01-07-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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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on the acceptance of a modification of an agreed paediatric investigation plan for ipilimumab (Yervoy), (EMEA-000117-PIP01-07-M06) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Councill

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/95/2008 issued on 3 November 2008, the decision P/92/2010 issued on 2 June 2010, the decision P/151/2011 issued on 10 June 2011, the decision P/264/2011 issued on 28 October 2011, the decision P/0115/2012 issued on 2 July 2012, and P/0195/2013 issued on 2 September 2013,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 16 December 2013 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 21 March 2014, 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 ipilimumab (Yervoy), 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 agreed PIP covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/128/2011 issued on 8 June 2011, including subsequent modifications thereof.

Article 3

This decision is addressed to Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, UB8 1DH - Uxbridge, United Kingdom.

Done at London, 7 April 2014

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

EMA/PDCO/18584/2014

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

EMEA-000117-PIP01-07-M06

Scope of the application

Active substance(s):

Ipilimumab

Invented name:

Yervoy

Condition(s):

Treatment of all conditions included in the category of malignant neoplasms (except melanoma, nervous system, haematopoietic and lymphoid tissue)

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 16 December 2013 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/95/2008 issued on 3 November 2008, the decision P/92/2010 issued on 2 June 2010, the decision P/151/2011 issued on 10 June 2011, the decision P/264/2011 issued on 28 October 2011, the decision P/0115/2012 issued on 2 July 2012 and the decision P/0195/2013 issued on 2 September 2013.

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

The procedure started on 21 January 2014.

Scope of the modification

Some measures and a timeline 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 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.

London, 21 March 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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. Condition: treatment of all conditions included in the category of malignant neoplasms (except melanoma, nervous system, haematopoietic and lymphoid tissue)

2.2. Indication(s) targeted by the PIP

Treatment of solid malignant tumours (refractory to standard therapy).

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

From birth to less than 18 years of age.

2.2.2. Pharmaceutical form(s)

Concentrate for solution for infusion.

2.2.3. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	**Study 1:** Open label, dose escalation, tolerability, toxicity and pharmacokinetic clinical trial of intravenously administered ipilimumab in patients aged from 2 to less than 18 years (and in young adults to 21 years) with untreatable, refractory or relapsed solid malignant tumours. **Study 2:** Randomised, controlled, double-blind, parallel group pharmacokinetic, safety and efficacy clinical trial of ipilimumab in patients aged from 0 to less than 18 years with solid malignant tumours based on the results of the phase I study (Measure 1).

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 2015
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 who have received prior therapy.

Authorised pharmaceutical form(s):

Concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use