EMA/215073/2015

# European Medicines Agency decision

P/0085/2015

of 8 May 2015

on the acceptance of a modification of an agreed paediatric investigation plan for ipilimumab (Yervoy), (EMEA-000117-PIP01-07-M07) 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.**

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Contact EMA** www.ema.europa.eu/contact

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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/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, the decision P/0195/2013 issued on 2 September 2013, and the decision P/0092/2014 issued on 7 April 2014,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 22 December 2014 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 20 March 2015, in accordance with Article 22 of Regulation (EC) No 1901/2006, and of its own motion in accordance with Article 12 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 acceptance of changes to the agreed paediatric investigation plan and to the deferral and on the granting of a waiver.

(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.

(3) It is therefore appropriate to adopt a decision on the granting of 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***

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***

A waiver for ipilimumab (Yervoy), concentrate for solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

***Article 3***

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 4***

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

Done at London, 8 May 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/18584/2014
London, 20 March 2015

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-000117-PIP01-07-M07

## 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

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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 22 December 2014 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, the decision P/0195/2013 issued on 2 September 2013, and the decision P/0092/2014 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 20 January 2015.

## Scope of the modification

Some measures and the timelines of the Paediatric Investigation Plan have been modified and a waiver was granted.

## 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.

   And in accordance with Article 12 of Regulation (EC) No 1901/2006 as amended, recommends to grant a product-specific waiver for the subsets specified in the Annex I of this opinion concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely ineffective or unsafe in part or all of the paediatric population.

   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 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

## *1.1. Condition*

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

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- for concentrate for solution for infusion, intravenous use;
- on the grounds that the specific medicinal product is likely to be ineffective.

# 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 a solid malignant tumour (refractory to standard therapy)

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

From 2 years 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 | 1 | **Study 1**<br>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. |

## 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 February 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.

## Authorised pharmaceutical form(s)

Concentrate for solution for infusion

## Authorised route(s) of administration

Intravenous use