



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/849026/2011

## European Medicines Agency decision P/265/2011

of 28 October 2011

on the acceptance of a modification of an agreed paediatric investigation plan for ipilimumab (Yervoy) (EMA-000117-PIP02-10-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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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<sup>1</sup>,

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<sup>2</sup>,

Having regard to the European Medicines Agency's decision P/128/2011 issued on 8 June 2011,

Having regard to the application submitted by Bristol-Myers Squibb International Corporation 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 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.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1.

<sup>2</sup> 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 International Corporation, Parc de l'Alliance, Avenue de Finlande 8, 1420 Braine-l'Alleud, Belgium.

Done at London, 28 October 2011

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



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/674966/2011

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

EMA-000117-PIP02-10-M01

### 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 International Corporation

### Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bristol-Myers Squibb International Corporation 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/128/2011 issued on 8 June 2011.



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

The procedure started on 13 July 2011.

### **Scope of the modification**

Some measures and/or timelines of the paediatric investigation plan and deferral 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 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. 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. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	<b>Study 1</b> Intravenous study of pre- and postnatal development in cynomolgus monkeys with a 6-month postnatal evaluation.
Clinical	3	<b>Study 2</b> 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. <b>Study 3</b> 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. <b>Study 4</b> Open-label randomized active-controlled study of adjuvant ipilimumab anti-CTLA4 therapy versus high-dose interferon $\alpha$ -2b in children aged 12 to less than 18 years (and adults) with resected high-risk melanoma.

### 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 2017
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 indications: YERVOY is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy.

<b>EU number</b>	<b>Invented name</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>	<b>Packaging</b>	<b>Content (concentration)</b>	<b>Package size</b>
EU/1/11/698/001	Yervoy	5 mg/ml	Concentrate for solution for infusion	Intravenous use	vial (glass)	10 ml	1 vial
EU/1/11/698/002	Yervoy	5 mg/ml	Concentrate for solution for infusion	Intravenous use	vial (glass)	40 ml	1 vial