



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/440862/2011

## European Medicines Agency decision P/151/2011

of 10 June 2011

on the acceptance of a modification of an agreed paediatric investigation plan for ipilimumab (EMA-000117-PIP01-07-M02) 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/95/2008, issued on 3 November 2008 and the decision P/92/2010 issued on 2 June 2010,

Having regard to the application submitted by Bristol-Myers Squibb International Corporation on 28 April 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 20 May 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.

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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, 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 Bristol-Myers Squibb International Corporation, Parc de l'Alliance, Avenue de Finlande 8, 1420 - Braine-l'Alleud, Belgium.

Done at London, 10 June 2011

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



EUROPEAN MEDICINES AGENCY  
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EMA/PDCO/364937/2011

## Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000117-PIP01-07-M02

### **Scope of the application**

#### **Active substance(s):**

Ipilimumab

#### **Condition(s):**

Treatment of solid malignant tumours excluding melanoma

#### **Pharmaceutical form(s):**

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 28 April 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/95/2008 of 3 November 2008 and decision P/92/2010 of 2 June 2010.

The application for modification proposed changes.

The procedure started on 18 May 2011.

### **Scope of the modification**

Some measures and/or timelines of the original opinion 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 proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan.

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, 20 May 2011

On behalf of the Paediatric Committee

Dr Daniel Brasseur, Chairman

(Signature on file)

## **Annex I**

### **The measures and timelines of the agreed paediatric investigation plan**

## 1. Condition(s)

Treatment of solid malignant tumours excluding melanoma

## 2. Waiver

Not applicable.

## 3. Paediatric Investigation Plan

### 3.1. Condition to be investigated

Treatment of solid malignant tumours excluding melanoma

#### 3.1.1. Indication targeted by the PIP

Treatment of solid malignant tumours (refractory to standard therapy)

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

From 0 to less than 18 years.

#### 3.1.3. Pharmaceutical form(s)

Solution for infusion

#### 3.1.4. Studies

Area	Number of studies	Description
Clinical	1	Open label, dose escalation, tolerability, toxicity and pharmacokinetic clinical trial of intravenously administered ipilimumab in patients aged from 3 to less than 18 years (and in young adults to 21 years) with untreatable, refractory or relapsed solid malignant tumours.
Clinical	1	Randomised, double-blind, parallel group pharmacokinetic, safety and efficacy clinical trial of ipilimumab in patients aged from 0 to less than 18 years based on the results of the phase I study.

## 4. Follow-up, completion and deferral of PIP

<b>Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:</b>	<b>Yes</b>
Date of completion of the paediatric investigation plan:	By March 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes