EMA/337445/2010

European Medicines Agency decision

P/92/2010

of 2 June 2010

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
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 (EMEA-000117-PIP01-07-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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,

Having regard to the application submitted by Bristol-Myers Squibb International Corporation on 23 February 2010 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 16 April 2010, 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, 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, 2 June 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

EMA/337445/2010

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

EMEA-000117-PIP01-07-M01

Scope of the application

Active substance(s):

Ipilimumab

Condition(s):

Solid malignant tumours

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 23 February 2010 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. The application for modification proposed changes.

The procedure started on 23 March 2010.

Scope of the modification

Some measures and/or timelines of the original opinion have been modified.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
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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, 16 April 2010

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)

Solid malignant tumours

2. Waiver

Not applicable.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Solid malignant tumours

3.1.1. Indication targeted by the PIP

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

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