



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/791990/2015

European Medicines Agency decision

P/0319/2015

of 21 December 2015

on the granting of a product specific waiver for recombinant human monoclonal IgG1 antibody directed against Programmed Death Ligand-1 (anti-PD-L1) (MSB0010718C) (EMA-001849-PIP01-15) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Merck KGaA on 6 August 2015 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 November 2015 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.
- (2) It is therefore appropriate to adopt a decision granting 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

A waiver for recombinant human monoclonal IgG1 antibody directed against Programmed Death Ligand-1 (anti-PD-L1) (MSB0010718C), concentrate for solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 2

This decision is addressed to Merck KGaA, Frankfurter Strasse 250, 64293 - Frankfurt, Germany.

Done at London, 21 December 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/587237/2015
London, 13 November 2015

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMA-001849-PIP01-15

Scope of the application

Active substance(s):

Recombinant human monoclonal IgG1 antibody directed against Programmed Death Ligand-1 (anti-PD-L1) (MSB0010718C)

Condition(s):

Treatment of Merkel cell carcinoma

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name / corporate name of the PIP applicant:

Merck KGaA

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Merck KGaA submitted to the European Medicines Agency on 6 August 2015 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 15 September 2015.

A meeting with the Paediatric Committee took place on 12 November 2015.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to grant a product-specific waiver for all subsets of the paediatric population and all the above mentioned condition(s) in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population and Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of Merkel cell carcinoma

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 disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

The waiver applies to:

- The paediatric population from 2 years to less than 18 years of age;
- for concentrate for solution for infusion, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.