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European Medicines Agency decision

P/0032/2017

of 31 January 2017

on the granting of a product specific waiver for mirvetuximab soravtansine (EMEA-001921-PIP01-16) 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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on the granting of a product specific waiver for mirvetuximab soravtansine (EMEA-001921-PIP01-16) 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 application submitted by ImmunoGen Europe Limited on 9 September 2016 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 16 December 2016 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.

Has adopted this decision:

Article 1

A waiver for mirvetuximab soravtansine, solution for injection/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 ImmunoGen Europe Limited, 24 Chiswell Street, Third Floor, EC1Y - 4YX London, United Kingdom.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/665232/2016
London, 16 December 2016

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

EMEA-001921-PIP01-16

Scope of the application

Active substance(s):

Mirvetuximab soravtansine

Condition(s):

Treatment of ovarian carcinoma

Treatment of Fallopian tube carcinoma

Treatment of peritoneal carcinoma

Pharmaceutical form(s):

Solution for injection/infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

ImmunoGen Europe Limited

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, ImmunoGen Europe Limited submitted to the European Medicines Agency on 9 September 2016 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 18 October 2016.

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 conditions 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 annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of ovarian carcinoma

The waiver applies to:

- All boys from birth to less than 18 years of age and girls from birth to less than 4 years of age;
- for solution for injection/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:

- Girls from 4 to less than 18 years of age;
- for solution for injection/infusion, intravenous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

1.2. Condition:

Treatment of Fallopian tube carcinoma

The waiver applies to:

- All boys from birth to less than 18 years of age and girls from birth to less than 12 years of age;
- for solution for injection/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:

- Girls from 12 to less than 18 years of age;
- for solution for injection/infusion, intravenous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

1.3. Condition:

Treatment of peritoneal carcinoma

The waiver applies to:

- All boys from birth to less than 18 years of age and female population from birth to less than 12 years of age;
- for solution for injection/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:

- Girls from 12 to less than 18 years of age;
- for solution for injection/infusion, intravenous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).