EMA/792666/2014

European Medicines Agency decision

P/0004/2015

of 30 January 2015

on the granting of a product specific waiver for everolimus (Certican and associated names), (EMEA-000019-PIP11-14) 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 726/2004[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 Novartis Europharm Ltd on 5 August 2014 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 12 December 2014 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 everolimus (Certican and associated names), tablet, dispersible tablet, oral 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 Novartis Europharm Ltd, Frimley Business Park, GU16 7SR - Camberley, United Kingdom.

Done at London, 30 January 2015

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

EMA/PDCO/546463/2014

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

EMEA-000019-PIP11-14

Scope of the application

Active substance(s):

Everolimus

Invented name:

Certican and associated names

Condition(s):

Treatment of thoracic neuroendocrine tumour

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Dispersible tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis Europharm Ltd

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Ltd submitted to the European Medicines Agency on 5 August 2014 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 14 October 2014.

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 the above mentioned condition(s) in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   The Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 12 December 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of thoracic neuroendocrine tumour

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for tablet and dispersible tablet, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of breast cancer

Authorised indication:

- Afinitor is indicated for the treatment of hormone receptor-positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.

2. Treatment of neuroendocrine tumours of pancreatic origin

Authorised indication:

- Afinitor is indicated for the treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin in adults with progressive disease.

3. Treatment of renal cell carcinoma

Authorised indication:

- Afinitor is indicated for the treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with VEGF-targeted therapy.

4. Prevention of rejection of transplanted kidney

- Certican is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogeneic renal or cardiac transplant. In kidney and heart transplantation, Certican should be used in combination with ciclosporin for microemulsion and corticosteroids.

5. Prevention of rejection of transplanted heart

Authorised indication:

- Certican is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogeneic renal or cardiac transplant. In kidney and heart transplantation, Certican should be used in combination with ciclosporin for microemulsion and corticosteroids.

6. Prevention of rejection of transplanted liver

Authorised indication:

- Certican is indicated for the prophylaxis of organ rejection in patients receiving a hepatic transplant. In liver transplantation, Certican should be used in combination with tacrolimus and corticosteroids.

Authorised pharmaceutical form(s):

Tablet

Dispersible tablet

Authorised route(s) of administration:

Oral use