



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/656487/2010

European Medicines Agency decision P/207/2010

of 29 October 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for everolimus (Certican, Afinitor and associated names), (EMEA-000019-PIP06-09) 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 726/2004¹,

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 Novartis Europharm Limited on 10 September 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 September 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) 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 paediatric investigation plan for everolimus (Certican, Afinitor and associated names), tablet, dispersible tablet, age appropriate liquid formulation, 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 agreed.

Article 2

A deferral for everolimus (Certican, Afinitor and associated names), tablet, dispersible tablet, age appropriate liquid formulation, 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 3

A waiver for everolimus (Certican, Afinitor and associated names), tablet, dispersible tablet, age appropriate liquid formulation, 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 4

This decision is addressed to Novartis Europharm Limited, Wimblehurst Road, RH12 5AB Horsham, West Sussex, United Kingdom.

Done at London, 29 October 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/475624/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-000019-PIP06-09

Scope of the application

Active substance(s):

Everolimus

Invented name:

Certican, Afinitor and associated names

Condition(s):

Prevention of rejection of transplanted kidney

Prevention of rejection of transplanted heart

Authorised indication(s): see Annex II

Pharmaceutical form(s):

Tablet

Dispersible tablet

Age appropriate liquid formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Information about the authorised medicinal product: see Annex II



Basis for opinion

Pursuant to Article 16(1)) of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted for agreement to the European Medicines Agency on 10 September 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 15 October 2009.

Supplementary information was provided by the applicant on 25 June 2010.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
- to grant a deferral in accordance with Article 21 of said Regulation ,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded 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.

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 agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver 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, 10 September 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 and the subset(s) of the paediatric population and condition(s) covered by the waiver

1. Waiver

1.1. Condition(s)

Prevention of rejection of transplanted kidney

Prevention of rejection of transplanted heart

The waiver applies to:

- Children from birth to less than 12 months
- for tablet, dispersible tablet, age appropriate liquid formulation for oral 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).

2. Paediatric Investigation Plan

2.1. Condition to be investigated

Prevention of rejection of transplanted kidney

2.1.1. Indication(s) targeted by the PIP

Prevention of acute rejection in de novo paediatric recipients of a renal transplant from 1 to less than 18 years old.

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

From 1 year to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Tablet, dispersible tablet, age appropriate liquid formulation

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Development of age appropriate oral liquid formulation (same as for condition Prevention of rejection of transplanted heart).
Non-clinical	0	Not applicable.
Clinical	1	Study 2 Open label, randomised, multicentre study to evaluate efficacy, tolerability and safety of everolimus in paediatric kidney transplant recipients from 1 to less than 18 years old.

2.2. Condition to be investigated

Prevention of rejection of transplanted heart

2.2.1. Indication(s) targeted by the PIP

Prevention of acute rejection in paediatric recipients of a heart transplant from 1 to less than 18 years old.

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

From 1 year to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Tablet, dispersible tablet, age appropriate liquid formulation

2.2.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Development of age appropriate oral liquid formulation (same as for condition Prevention of rejection of transplanted kidney).
Non-clinical	0	Not applicable.
Clinical	1	Study 3 Open label, randomised, multicentre study to evaluate efficacy, tolerability and safety of everolimus in paediatric heart transplant recipients from 1 to less than 18 years old.

3. 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 June 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

EU Number	(Invented) name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content (concentration)	Package size
EU/1/09/538/001	Afinitor	5 mg	Tablet	Oral use	blister (alu/PA/alu/PVC)		30 tablets
EU/1/09/538/002	Afinitor	5 mg	Tablet	Oral use	blister (alu/PA/alu/PVC)		60 tablets
EU/1/09/538/003	Afinitor	5 mg	Tablet	Oral use	blister (alu/PA/alu/PVC)		90 tablets
EU/1/09/538/004	Afinitor	10 mg	Tablet	Oral use	blister (alu/PA/alu/PVC)		30 tablets
EU/1/09/538/005	Afinitor	10 mg	Tablet	Oral use	blister (alu/PA/alu/PVC)		60 tablets
EU/1/09/538/006	Afinitor	10 mg	Tablet	Oral use	blister (alu/PA/alu/PVC)		90 tablets
EU/1/09/538/007	Afinitor	5 mg	Tablet	Oral use	blister (alu/PA/alu/PVC)		10 tablets
EU/1/09/538/008	Afinitor	10 mg	Tablet	Oral use	blister (alu/PA/alu/PVC)		10 tablets

Invented name Name	Strength	Pharmaceutical form	Route of administration
Certican associated names	0.1, 0.25, 0.5, 0.75 and 1.0 mg	Tablet and dispersible tablet	Oral use

RFM: Sweden for MRP

Decentralised / Mutual recognition / National procedure(s) (Outside EEA)

Invented name	Country	Authorised indication
Certican	Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland,	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. Certican should be used in combination with ciclosporin for microemulsion and corticosteroids.

	Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden	
Everolimus Novartis	Germany, Sweden	Everolimus Novartis is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogeneic renal or cardiac transplant. Everolimus Novartis should be used in combination with ciclosporin for microemulsion and corticosteroids