EMA/5126/2017

European Medicines Agency decision

P/0002/2017

of 12 January 2017

on the acceptance of a modification of an agreed paediatric investigation plan for belatacept (Nulojix), (EMEA-000157-PIP01-07-M03) 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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European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for belatacept (Nulojix), (EMEA-000157-PIP01-07-M03) 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/99/2008 issued on 3 November 2008, the decision P/0083/2012 issued on 16 May 2012 and the decision P/0080/2015 issued on 10 April 2015,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 23 September 2016 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 December 2016, 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 belatacept (Nulojix), powder for concentrate for 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 Pharma EEIG, Uxbridge Business Park, Sanderson Road, UB8 1DH - Uxbridge, United Kingdom.

EMA/PDCO/659394/2016
London, 16 December 2016

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

EMEA-000157-PIP01-07-M03

Scope of the application

Active substance(s):

Belatacept

Invented name:

Nulojix

Condition(s):

Prevention of rejection of transplanted kidney

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Bristol-Myers Squibb Pharma EEIG

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bristol-Myers Squibb Pharma EEIG submitted to the European Medicines Agency on 23 September 2016 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/99/2008 issued on 3 November 2008, the decision P/0083/2012 issued on 16 May 2012 and the decision P/0080/2015 issued on 10 April 2015.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 18 October 2016.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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 to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees 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 annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Prevention of rejection of transplanted kidney

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- for powder for concentrate for solution for infusion, intravenous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

The waiver applies to:

- the paediatric population from 6 years to less than 12 years;
- for powder for concentrate for solution for infusion, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

2. Paediatric investigation plan

2.1. Condition:

Prevention of rejection of transplanted kidney.

2.1.1. Indication(s) targeted by the PIP

Prevention of acute rejection following renal transplantation.

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

From 12 years to less than 18 years.

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion.

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	5	**Study 1:** Thirteen-week subcutaneous/intravenous toxicity study in juvenile rats **Study 2:** Three-month intermittent-dose subcutaneous and intravenous immunotoxicity study in juvenile rats **Study 3:** Three-month intermittent-dose intravenous immunotoxicity study in rats

		Study 4: In vitro evaluation of CD86 receptor occupancy in paediatric blood **Study 5:** Three-month intermittent-dose subcutaneous investigative immunotoxicity study in juvenile rats
Clinical studies	2	**Study 6:** Single-dose PK study in stable renal transplant recipients (from 12 to less than 18 years of age) receiving a calcineurin inhibitor (CNI)-based maintenance immunosuppressant therapy. (IM103144) **Study 7:** Multi-center, randomized conversion study to evaluate the safety, efficacy and pharmacokinetics of belatacept administered to adolescents aged 12 to less than 18 years with a stable renal transplant. (M103XXX)
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes.
Date of completion of the paediatric investigation plan:	By June 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of rejection of transplanted kidney

Authorised indication(s):

- Nulojix, in combination with corticosteroids and a mycophenolic acid (MPA), is indicated for prophylaxis of graft rejection in adults receiving a renal transplant

Authorised pharmaceutical form(s):

Powder for concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use