EMA/441696/2024

European Medicines Agency decision

P/0351/2024

of 27 September 2024

on the acceptance of a modification of an agreed paediatric investigation plan for belatacept (Nulojix), (EMEA-000157-PIP01-07-M06) 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.

European Medicines Agency decision

P/0351/2024

of 27 September 2024

on the acceptance of a modification of an agreed paediatric investigation plan for belatacept (Nulojix), (EMEA-000157-PIP01-07-M06) 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 Union procedures for the authorisation and supervision of medicinal products for human 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, the decision P/0080/2015 issued on 10 April 2015 and the decision P/0002/2017 issued on 12 January 2017, decision P/0260/2019 issued on 16 July 2019.and the decision P/0277/2020 issued on 15 July 2020,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 30 May 2024 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 6 September 2024, 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

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

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, including changes to the deferral, 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, Plaza 254, Blanchardstown Corporate Park 2, D15 T867 - Dublin 15, Ireland.

EMA/PDCO/278915/2024
Amsterdam, 6 September 2024

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

EMEA-000157-PIP01-07-M06

Scope of the application

Active substance(s):

Belatacept

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of rejection of transplanted kidney

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

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 30 May 2024 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, the decision P/0080/2015 issued on 10 April 2015 and the decision P/0002/2017 issued on 12 January 2017, decision P/0260/2019 issued on 16 July 2019.and the decision P/0277/2020 issued on 15 July 2020.

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

The procedure started on 8 July 2024.

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 and to the deferral in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the 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 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

Prophylaxis of graft rejection in combination with corticosteroids and/or a mycophenolic acid for paediatric patients from 12 years of age and older with a stable renal transplant for at least 6 months who convert to a CNI-free maintenance treatment

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	Description
Quality-related studies	Not applicable
Non-clinical studies	**Study 1** Thirteen-week subcutaneous/intravenous toxicity study in juvenile rats (Study DN07013)

	Study 2 Three-month intermittent-dose subcutaneous and intravenous immunotoxicity study in juvenile rats (Study DS07165) **Study 3** Three-month intermittent-dose intravenous immunotoxicity study in rats (Study DS07166) **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 (DN11153)
Clinical studies	**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 functionally stable renal transplant in the short term. (M103XXX)
Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	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 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

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 adult recipients of a renal transplant.
  - Invented name(s): Nulojix
  - Authorised pharmaceutical form(s): Powder for concentrate for solution for infusion
  - Authorised route(s) of administration: Intravenous use
  - Authorised via centralised procedure.