MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (EMEA-000157-PIP01-07-M05) and to the deferral

MHRA-101482-PIP01-24-M01

Scope of the Application

Active Substance(s)

BELATACEPT

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 the Decision

Pursuant to the Human Medicines Regulations 2012, Bristol-Myers Squibb Pharma EEIG submitted to the licensing authority on 13/06/2024 08:08 BST an application for a Modification

The procedure started on 03/09/2024 08:32 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101482-PIP01-24-M01

Of 08/10/2024 14:04 BST

On the adopted decision for BELATACEPT (MHRA-101482-PIP01-24-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for BELATACEPT, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Bristol-Myers Squibb Pharma EEIG, Plaza 254 Blanchardstown Corporate Park 2 Dublin 15, Dublin, IRELAND, D15 T867

ANNEX I

1. Waiver

1.1 Condition:

Prevention of rejection of transplanted kidney The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age Pharmaceutical form(s): Powder for concentrate for solution for infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: For the paediatric population from birth to less than 6 years of age: - on the grounds that the specific medicinal product is likely to be unsafe. For the paediatric population from 6 years to less than 12 years of age: - on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of rejection of transplanted kidney

2.2 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

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 12 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder for concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	5	Study 1 (Study DN07013) Thirteen-week subcutaneous/intravenous toxicity study in juvenile rats. Study 2 (Study DS07165) Three-month intermittent-dose subcutaneous and intravenous immunotoxicity study in juvenile rats. Study 3 (Study DS07166) Three-month intermittent-dose intravenous immunotoxicity study in rats. Study 4 In vitro evaluation of CD86 receptor occupancy in paediatric blood. Study 5 (DN11153) Three-month intermittent-dose subcutaneous investigative immunotoxicity study in juvenile rats.
Clinical Studies	2	Study 6 (IM103144) Single-dose PK study in stable renal transplant recipients (from 12 years to less than 18 years of age) receiving a calcineurin inhibitor (CNI)-based maintenance immunosuppressant therapy. Study 7 (IM103-402) Multi-centre, randomised conversion study to evaluate the safety, efficacy and pharmacokinetics of belatacept

		administered to adolescents aged 12 years to less than 18 years with a functionally stable renal transplant in the short term.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	30/06/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes