MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-101413-PIP01-24)

MHRA-101413-PIP01-24-M01

Scope of the Application

Active Substance(s)

BLINATUMOMAB

Condition(s)

Treatment of acute lymphoblastic leukaemia

Pharmaceutical Form(s)

Powder for solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Amgen Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Amgen Limited submitted to the licensing authority on 18/08/2025 03:00 BST an application for a Modification

The procedure started on 02/09/2025 22:02 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

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-101413-PIP01-24-M01

Of 15/12/2025 16:39 GMT

On the adopted decision for BLINATUMOMAB (MHRA-101413-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 BLINATUMOMAB, Powder for solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Amgen Limited, 216 Cambridge Science Park, Milton Road , Cambridge, UNITED KINGDOM, CB4 0WA

ANNEX I

1. Waiver

1.1 Condition:

Treatment of acute lymphoblastic leukaemia The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 28 days of age Pharmaceutical form(s): Powder for solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of acute lymphoblastic leukaemia

2.2 Indication(s) targeted by the PIP:

Treatment of children with relapsed/ refractory and MRD+ B-cell precursor acute lymphoblastic leukaemia

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

The paediatric population from 28 days to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder for solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 1 (20180257) Open-label, uncontrolled, single arm study to evaluate safety, activity and pharmacokinetic (PK) parameters following subcutaneous (SC) administration of blinatumomab in adolescent patients from 12 years to less than 18 years of age (and adults) with relapsed or refractory and MRD+ B-cell precursor acute lymphoblastic leukaemia (R/R B-ALL). Study 2 (20220107) Open label, uncontrolled, single arm trial to evaluate safety and tolerability and determine the recommended Phase 2 dose (Phase 1) and evaluate the activity (Phase 2) of SC blinatumomab in patients from 28 days to less than 12 years of age with R/R and MRD+ B-ALL.
Extrapolation, Modeling & Simulation Studies	3	Study 3 Modelling and simulation population pharmacokinetic (Pop-PK) study to predict the initial paediatric doses to be used in further clinical studies in children from 28 days to less than 18 years of age with R/R B-ALL. Study 4 Modelling and simulation Pop-PK/PD study

		to confirm or modify the paediatric posology compared to the regimen used in clinical trials in children from 28 days to less than 18 years of age with R/R B-ALL. Extrapolation plan Study 1 (Study 20180257), Study 2 (Study 20220107) and Study 4 are part of an extrapolation plan covering the paediatric population from 28 days to less than 18 years of age.
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:	31/03/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes