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-100674-PIP01-22-M01)

MHRA-100674-PIP01-22-M02

Scope of the Application

Active Substance(s)

DARATUMUMAB

Condition(s)

Treatment of lymphoid malignancies (except mature B-cell neoplasms)

Pharmaceutical Form(s)

Concentrate for solution for infusion, Solution for injection

Route(s) of Administration

INTRAVENOUS USE; SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Janssen-Cilag Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Limited submitted to the licensing authority on 11/12/2024 14:53 GMT an application for a Modification

The procedure started on 17/12/2024 15:04 GMT

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-100674-PIP01-22-M02

Of 20/12/2024 16:22 GMT

On the adopted decision for DARATUMUMAB (MHRA-100674-PIP01-22-M02) 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 DARATUMUMAB, Concentrate for solution for infusion, Solution for injection , INTRAVENOUS USE; SUBCUTANEOUS USE .

This decision is addressed to Janssen-Cilag Limited, 50-100 Holmers Farm Way, Buckinghamshire, High Wycombe, UNITED KINGDOM, HP12 4EG

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of lymphoid malignancies (except mature B-cell neoplasms)

2.2 Indication(s) targeted by the PIP:

Treatment of paediatric patients from birth to less than 18 years of age with a lymphoid malignancy (except mature B-cell neoplasms)

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

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Concentrate for solution for infusion 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	1	Study 1 Multicentre, open-label study to evaluate safety, anti-tumour activity, and pharmacokinetics of daratumumab in combination therapy in paediatric patients from 1 year to less than 18 years of age (and adults) with acute lymphoblastic leukaemia (ALL)/ lymphoblastic lymphoma (LL). Study 2 Deleted during procedure MHRA-100674-PIP01-22-M01.
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:	No
Date of completion of the paediatric investigation plan:	31/10/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes