

**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 and to the deferral

MHRA-100674-PIP01-22-M01

### **Scope of the Application**

#### **Active Substance(s)**

DARATUMUMAB

#### **Condition(s)**

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

#### **Pharmaceutical Form(s)**

Solution for injection, Concentrate for solution for infusion

#### **Route(s) of Administration**

SUBCUTANEOUS USE; INTRAVENOUS 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 09/09/2022 12:01 BST an application for a Modification

The procedure started on 14/02/2023 15:17 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 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-100674-PIP01-22-M01

Of 06/03/2023 08:58 GMT

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

This decision is addressed to Janssen-Cilag Limited, 50-100 Holmers Farm Way, 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:	30/10/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes

