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-100268-PIP01-21-M01) and to the deferral

MHRA-100501-PIP01-22-M01

Scope of the Application

Active Substance(s)

INOTUZUMAB OZOGAMICIN

Condition(s)

Treatment of B cell acute lymphoblastic leukaemia

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

Pfizer Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 27/05/2022 11:35 BST an application for a Modification

The procedure started on 23/08/2022 10:18 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-100501-PIP01-22-M01

Of 31/08/2022 16:07 BST

On the adopted decision for INOTUZUMAB OZOGAMICIN (MHRA-100501-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 INOTUZUMAB OZOGAMICIN, Powder for concentrate for solution for infusion , Intravenous use .

This decision is addressed to Pfizer Limited , Ramsgate Road, Sandwich Kent , UNITED KINGDOM, CT13 9NJ

ANNEX I

1. Waiver

1.1 Condition:

Treatment of B cell acute lymphoblastic leukaemia The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age Pharmaceutical form(s): Powder for concentrate for solution for infusion Route(s) of administration: Intravenous use Reason for granting waiver: 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):

Treatment of B cell acute lymphoblastic leukaemia

2.2 Indication(s) targeted by the PIP:

For the treatment of relapsed or refractory B cell precursor acute lymphoblastic leukaemia

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

The paediatric population from 1 year 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	0	Not applicable
Clinical Studies	2	Study 1 Open-label, multiple dose, two strata trial to establish the maximum tolerated dose of inotuzumab ozogamicin used as single agent and as add-on to modified regimen from trial UKALL-R3 in children from 1 year to less than 18 years of age with CD22-positive relapsed/refractory acute lymphoblastic leukaemia. Study 2 Open-label, randomised superiority trial to evaluate safety and efficacy of inotuzumab ozogamicin monotherapy over standard UKALL-R3 regimen in patients from 1 year to less than 18 years of age (and adults) with high risk first relapse of CD22 positive B cell precursor acute lymphoblastic leukaemia.
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:	31/01/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes