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-100254-PIP01-21-M01

Scope of the Application

Active Substance(s)

epcoritamab

Condition(s)

Treatment of mature B-cell malignancies

Pharmaceutical Form(s)

Concentrate for solution for injection, Solution for injection

Route(s) of Administration

Subcutaneous use

Name / Corporate name of the PIP applicant

AbbVie Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AbbVie Ltd submitted to the licensing authority on 22/09/2022 13:11 BST an application for a Modification

The procedure started on 29/09/2022 18:54 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-100254-PIP01-21-M01

Of 07/10/2022 17:58 BST

On the adopted decision for epcoritamab (MHRA-100254-PIP01-21-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 epcoritamab, Concentrate for solution for injection, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to AbbVie Ltd, Abbvie House, Maidenhead, UNITED KINGDOM, SL6 4UB

ANNEX I

1. Waiver

1.1 Condition:

Treatment of mature B-cell lymphoma The waiver applies / applied to: Paediatric Subset(s): •The paediatric population from birth to less than 1 years Pharmaceutical form(s): Concentrate for solution for injection; Solution for injection Route(s) of administration: Subcutaneous use Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of mature B-cell malignancies

2.2 Indication(s) targeted by the PIP:

Treatment of paediatric patients with mature B cell lymphoma after failure of first line therapy.

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

The paediatric population from 1 years to less than 18 years

2.4 Pharmaceutical Form(s):

Concentrate for solution for injection; Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age appropriate dilution scheme
Non-Clinical Studies	0	Not Applicable
Clinical Studies	2	Study 2 (M20-429) Open-label, single-arm study to evaluate the pharmacokinetics, pharmacodynamics, safety, activity and immunogenicity of monotherapy epcoritamab in children from 1 year to less than 18 years old (and adults) with mature B cell neoplasms. Study 3 Open-label, randomised, active controlled trial to evaluate the safety, efficacy and immunogenicity of epcoritamab as add-on, or alternative to standard of care compared to standard of care in children from 1 year to less than 18 years of age (and adults) with mature B cell lymphoma.
Extrapolation, Modeling & Simulation Studies	1	Study 4 Modelling and simulation study to determine the dose of epcoritamab in the proposed paediatric indication in children from 1 year to less than 18 years with mature B cell lymphoma.
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:	30/06/2030

Deferral of one or more studies contained in the paediatric investigation plan:	Yes