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 grant a product specific waiver

MHRA-101079-PIP01-23-M01

Scope of the Application

Active Substance(s)

ZANUBRUTINIB

Condition(s)

Treatment of lymphoplasmacytic lymphoma, Treatment of mature B-cell neoplasms (excluding lymphoplasmacytic lymphoma)

Pharmaceutical Form(s)

Capsule, hard; Age appropriate oral solid dosage form.

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

BeiGene UK Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, BeiGene UK Ltd submitted to the licensing authority on 04/07/2023 21:22 BST an application for a Modification

The procedure started on 17/07/2023 15:42 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 grant a product specific waiver

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-101079-PIP01-23-M01

Of 19/07/2023 15:33 BST

On the adopted decision for ZANUBRUTINIB (MHRA-101079-PIP01-23-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 ZANUBRUTINIB, Capsule, hard; Age appropriate oral solid dosage form. , ORAL USE .

This decision is addressed to BeiGene UK Ltd, c/o TMF Group, 8th Floor 20 Farringdon Street, London, UNITED KINGDOM, EC4A 4AB

ANNEX I

1. Waiver

1.1 Condition:

1.1 Condition: Treatment of lymphoplasmacytic lymphoma The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Capsule, hard Age appropriate solid oral dosage form. Route(s) of administration: ORAL 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). 1.2 Condition: Treatment of mature B-cell neoplasms (excluding lymphoplasmacytic lymphoma) The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Capsule, hard Age appropriate solid oral dosage form. Route(s) of administration: ORAL USE Reason for granting waiver: For the paediatric population from birth to less than 1 year of age: 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). For the paediatric population from 1 year to less than 18 years of age: on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Studies 1 ,2 and 3 for the condition 'Treatment of mature B-cell neoplasms (excluding lymphoplasmacytic lymphoma)' were deleted during procedure MHRA-101079-PIP01-23-M01 and replaced with a full product specific waiver.

2.2 Indication(s) targeted by the PIP:

Not Applicable

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

Not Applicable

2.4 Pharmaceutical Form(s):

Not Applicable

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not Applicable
Non-Clinical Studies	0	Not Applicable
Clinical Studies	0	Not Applicable
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:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	