

**MHRA**  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
United Kingdom

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## **Decision Cover Letter**

### **Decision of the licensing authority to:**

grant a product specific waiver

MHRA-102164-PIP01-25

### **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)**

Film-coated tablets

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

ORAL USE

#### **Name / Corporate name of the PIP applicant**

BEONE MEDICINES UK, LTD.

#### **Basis for the Decision**

Pursuant to the Human Medicines Regulations 2012, BEONE MEDICINES UK, LTD. submitted to the licensing authority on 14/10/2025 17:14 BST an application for a Waiver

The procedure started on 27/10/2025 17:14 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 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-102164-PIP01-25

Of 03/11/2025 14:39 GMT

On the adopted decision for ZANUBRUTINIB (MHRA-102164-PIP01-25) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Granting a waiver in all age groups for the listed condition(s).

This decision applies to a Waiver for ZANUBRUTINIB, Film-coated tablets , ORAL USE .

This decision is addressed to BEONE MEDICINES UK, LTD., c/o Regus London Paddington, 2 Kingdom Street, London, UNITED KINGDOM, W2 6BD

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Treatment of lymphoplasmacytic lymphoma. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): Film-coated tablets 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): The paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Film-coated tablets 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):

Not Applicable.

**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		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

**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:	

