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

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

accept of change(s) to the agreed paediatric investigation plan.

MHRA-100910-PIP01-23-M03

# Scope of the Application

## Active Substance(s)

ABEMACICLIB

## Condition(s)

Treatment of glioma

## Pharmaceutical Form(s)

Film-coated tablet; Age-appropriate oral solid dosage form

## Route(s) of Administration

ORAL USE; GASTRIC USE

## Name / Corporate name of the PIP applicant

Eli Lilly Nederland B.V.

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Eli Lilly Nederland B.V. submitted to the licensing authority on 24/12/2024 13:09 GMT an application for a Modification

The procedure started on 12/02/2025 10:09 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.

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-100910-PIP01-23-M03

Of 19/03/2025 14:39 GMT

On the adopted decision for ABEMACICLIB (MHRA-100910-PIP01-23-M03) 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 ABEMACICLIB, Film-coated tablet; Age-appropriate oral solid dosage form , ORAL USE; GASTRIC USE .

This decision is addressed to Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, Netherlands, Utrecht, NETHERLANDS, 3528 BJ

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Not applicable. |

### 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

| |
|---|
| Treatment of glioma Treatment of neuroblastoma was deleted during procedure MHRA-100910-PIP01-23-M03. |

### 2.2 Indication(s) targeted by the PIP:

| |
|---|
| Treatment of newly diagnosed patients with high grade glioma. |

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

| |
|---|
| The paediatric population from birth to less than 18 years of age. |

### 2.4 Pharmaceutical Form(s):

| |
|---|
| Film-coated tablet Age-appropriate oral solid dosage form |

### 2.5 Studies:

| Study Type | Number of Studies | Study Description |
|---|---|---|
| **Quality Measures** | 2 | Study 1 Development of an age-appropriate film-coated tablet. Study 2 Development of an age-appropriate oral solid dosage form. |
| **Non-Clinical Studies** | 1 | Study 3 (Juvenile toxicity study) Juvenile toxicity study to assess potential brain and pancreas toxicity of abemaciclib following repeated dosing to juvenile rats. |
| **Clinical Studies** | 2 | Study 4 (Dose escalation study) Open-label, dose-escalation trial to evaluate pharmacokinetics, safety and tolerability of abemaciclib in combination with irinotecan and temozolomide (triplet combination) and abemaciclib in combination with temozolomide (doublet combination) in children less than 18 years of age and weighing at least 10 kg and with BSA at least 0.5 m2 (and adults) with relapsed or refractory solid tumours. Study 5 (Newly diagnosed HGG) Open-label, randomised, controlled study to evaluate safety and efficacy of abemaciclib in combination with temozolomide, compared to temozolomide monotherapy, in children from birth to less than 18 years of age (and adults) with newly diagnosed high-grade glioma (HGG) following radiotherapy. Study 7 (Relapsed/ refractory NBL) This study was deleted during procedure MHRA-100910-PIP01-23-M03. |

| | | |
|---|---|---|
| **Extrapolation, Modeling & Simulation Studies** | 1 | Study 6 Modelling and simulation study to develop a mechanistic population PK model to define PK parameters of the product in children from birth to less than 18 years of age. |
| **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:** | 30/06/2028 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | No |