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-100909-PIP01-23-M02

Scope of the Application

Active Substance(s)

ABEMACICLIB

Condition(s)

Treatment of Ewing's sarcoma

Pharmaceutical Form(s)

Film-coated tablet

Route(s) of Administration

ORAL 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 13/02/2025 16:41 GMT an application for a Modification

The procedure started on 11/03/2025 09:27 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-100909-PIP01-23-M02

Of 01/04/2025 10:21 BST

On the adopted decision for ABEMACICLIB (MHRA-100909-PIP01-23-M02) 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 , ORAL 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:

Treatment of Ewing's sarcoma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age. Pharmaceutical form(s): Film-coated tablet Route(s) of administration: Oral Use Reason for granting waiver: On the grounds the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Ewing's sarcoma.

2.2 Indication(s) targeted by the PIP:

Treatment of relapsed/refractory Ewing's sarcoma in combination with irinotecan and temozolomide.

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):

Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of 25 mg film-coated tablets for paediatric use.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 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 body surface area (BSA) being at least 0.5 m2 (and adults) with relapsed or refractory solid tumours. Study 3 Open-label, randomised, controlled trial to evaluate efficacy, safety, pharmacokinetics and acceptability/ palatability of abemaciclib plus temozolomide plus irinotecan compared to temozolomide plus irinotecan in children from 1 year to less than 18 years of age (and adults) with relapsed or refractory Ewing's sarcoma.
Extrapolation, Modeling & Simulation Studies	1	Study 4 Modelling and simulation study to evaluate the use of the product in the proposed paediatric indication in children from 1 year to less than 18 years of age (and adults) with Ewing's sarcoma.

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:	30/09/2028
Deferral of one or more studies contained in the paediatric investigation plan:	No