

EMA/182989/2019

## European Medicines Agency decision P/0124/2019

of 17 April 2019

on the agreement of a paediatric investigation plan and on the granting of a waiver for abemaciclib (Verzenios), (EMA-002342-PIP01-18) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

### **Disclaimer**

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004<sup>1</sup>,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>2</sup>,

Having regard to the application submitted by Eli Lilly and Company on 26 March 2018 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 1 March 2019, in accordance with Article 17 of Regulation (EC) No 1901/2006 and of its own motion in accordance with Article 12 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a waiver.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

**Article 1**

A paediatric investigation plan for abemaciclib (Verzenios), film-coated tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

**Article 2**

A product-specific waiver for abemaciclib (Verzenios), film-coated tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

**Article 3**

This decision is addressed to Eli Lilly and Company Limited, Lilly Research Centre, Erl Wood Manor, Sunninghill Road, GU20 6PH – Windlesham, United Kingdom.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/843592/2018 Corr  
London, 1 March 2019

## Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMA-002342-PIP01-18

### Scope of the application

**Active substance(s):**

Abemaciclib

**Invented name:**

Verzenios

**Condition(s):**

Treatment of Ewing's Sarcoma

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Film-coated tablet

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

Eli Lilly and Company Limited

**Information about the authorised medicinal product:**

See Annex II

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company Limited submitted for agreement to the European Medicines Agency on 26 March 2018 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.



The procedure started on 2 May 2018.

Supplementary information was provided by the applicant on 26 November 2018. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

## Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
  - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
  - to grant a waiver for one or more subsets of the paediatric population on its own motion in accordance with Article 12 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

## **Annex I**

**The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)**

## 1. Waiver

### 1.1. Condition:

Treatment of Ewing's sarcoma

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- film-coated tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

## 2. Paediatric investigation plan

### 2.1. Condition:

Treatment of Ewing's Sarcoma

#### 2.1.1. Indication(s) targeted by the PIP

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

#### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 1 year to less than 18 years of age

#### 2.1.3. Pharmaceutical form(s)

Film-coated tablet

#### 2.1.4. Measures

| Area                    | Number of measures | Description                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Quality-related studies | 1                  | <b>Study 1</b><br>Development of 25 mg film-coated tablets for paediatric use                                                                                                                                                                                                                                                                                                                  |
| Non-clinical studies    | 0                  | Not applicable                                                                                                                                                                                                                                                                                                                                                                                 |
| Clinical studies        | 2                  | <b>Study 2</b><br>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 20 kg (and adults) with relapsed or refractory solid tumours |

|                                                 |   |                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                 |   | <b>Study 3</b><br><br>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, modelling and simulation studies | 1 | <b>Study 4</b><br><br>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 PIP

|                                                                                       |                   |
|---------------------------------------------------------------------------------------|-------------------|
| Concerns on potential long term safety/efficacy issues in relation to paediatric use: | Yes               |
| Date of completion of the paediatric investigation plan:                              | By September 2028 |
| Deferral for one or more measures contained in the paediatric investigation plan:     | No                |

## **Annex II**

### **Information about the authorised medicinal product**

**Condition(s) and authorised indication(s):**

1. Treatment of breast cancer

Authorised indication(s):

- Treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.

**Authorised pharmaceutical form(s):**

Film-coated tablet

**Authorised route(s) of administration:**

Oral use