

EMA/178738/2024

## European Medicines Agency decision

P/0169/2024

of 6 May 2024

on the agreement of a paediatric investigation plan and on the granting of a waiver for nivolumab / relatlimab (Opdualag), (EMEA-002727-PIP03-23) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency<sup>2</sup>,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 30 June 2023 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 22 March 2024, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 13 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, as amended.

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

Has adopted this decision:

**Article 1**

A paediatric investigation plan for nivolumab / relatlimab (Opdualag), solution for injection, subcutaneous 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 waiver for nivolumab / relatlimab (Opdualag), solution for injection, subcutaneous 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0326/2020 issued on 14 August 2020, including subsequent modifications thereof.

**Article 4**

This decision is addressed to Bristol-Myers Squibb Pharma EEIG, Plaza 254, Blanchardstown Corporate Park 2, D15 T867 - Dublin 15, Ireland.

EMA/PDCO/12715/2024  
Amsterdam, 22 March 2024

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

EMA-002727-PIP03-23

### Scope of the application

**Active substance(s):**

Nivolumab / relatlimab

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of melanoma

**Pharmaceutical form(s):**

Solution for injection

**Route(s) of administration:**

Subcutaneous use

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

Bristol-Myers Squibb Pharma EEIG

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Bristol-Myers Squibb Pharma EEIG submitted for agreement to the European Medicines Agency on 30 June 2023 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 14 August 2023.

Supplementary information was provided by the applicant on 15 December 2023. The applicant proposed modifications to the paediatric investigation plan.

## 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 in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

The Paediatric Committee member of Norway 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 melanoma

The waiver applies to:

- the paediatric population from birth to less than 12 years of age;
- solution for injection, subcutaneous use;
- 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).

# 2. Paediatric investigation plan

## 2.1. Condition:

Treatment of melanoma

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

Treatment of adolescents from 12 years to less than 18 years of age with unresectable or metastatic melanoma

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

From 12 years to less than 18 years of age.

### 2.1.3. Pharmaceutical form(s)

Solution for injection

### 2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Not applicable
Modelling and simulation analyses	<b>Study 1</b>  Modelling and simulation study to determine the dose of relatlimab / nivolumab fixed dose combination solution for injection and subcutaneous use, to be used in paediatric patients from 12 years to less than 18 years of age with unresectable or metastatic melanoma
Other studies	Not applicable

Extrapolation plan	Study 1, study CA224-127 (in participants from 12 years of age and older with previously untreated metastatic or unresectable melanoma) and other relevant paediatric and adult studies are part of the extrapolation plan of efficacy and safety data by exposure matching from adults covering the paediatric population from 12 years to less than 18 years of age, as agreed by the PDCO.
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### 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 June 2026
Deferral for one or more measures contained in the paediatric investigation plan:	No



## **Annex II**

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

***Information provided by the applicant:***

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

1. Treatment of melanoma

Authorised indication(s):

- Opdualag is indicated for the first-line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older with tumour cell PD-L1 expression < 1%
  - Invented name(s): Opdualag
  - Authorised pharmaceutical form(s): concentrate for solution for infusion
  - Authorised route(s) of administration: intravenous use
  - Authorised via centralised procedure.