



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/177600/2023

## European Medicines Agency decision P/0174/2023

of 15 May 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for vibostolimab/pembrolizumab, (EMEA-003063-PIP02-22) 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 Merck Sharp & Dohme (Europe) Inc. on 4 July 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 March 2023, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation 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 deferral 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 deferral.
- (4) 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 vibostolimab/pembrolizumab, concentrate for solution for infusion, intravenous 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 deferral for vibostolimab/pembrolizumab, concentrate for solution for infusion, intravenous 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**

A waiver for vibostolimab/pembrolizumab, concentrate for solution for infusion, intravenous 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 4**

This decision is addressed to Merck Sharp & Dohme (Europe) Inc., 5 Lynxbinnenhof, 1200 – Brussels, Belgium.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/3502/2023  
Amsterdam, 31 March 2023

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

EMA-003063-PIP02-22

### Scope of the application

#### Active substance(s):

Vibostolimab / pembrolizumab

#### Invented name and authorisation status:

See Annex II

#### Condition(s):

Treatment of Hodgkin lymphoma

#### Pharmaceutical form(s):

Concentrate for solution for infusion

#### Route(s) of administration:

Intravenous use

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

Merck Sharp & Dohme (Europe) Inc.

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe) Inc. submitted for agreement to the European Medicines Agency on 4 July 2022 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 16 August 2022.

Supplementary information was provided by the applicant on 15 December 2022. 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 deferral in accordance with Article 21 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)(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 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 Hodgkin lymphoma

The waiver applies to:

- the paediatric population from birth to less than 3 years of age;
- concentrate for solution for infusion, intravenous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

# 2. Paediatric investigation plan

## 2.1. Condition:

Treatment of Hodgkin lymphoma

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

Treatment of relapsed or refractory classical Hodgkin lymphoma in paediatric patients from 3 years of age to less than 18 years of age

Treatment of newly-diagnosed classical Hodgkin lymphoma in paediatric patients from 3 years of age to less than 18 years of age

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

From 3 years to less than 18 years of age.

### 2.1.3. Pharmaceutical form(s)

Concentrate for solution for infusion

### 2.1.4. Measures

Area	Description
Quality-related studies	<b>Study 1</b> Development of an age-appropriate formulation for the paediatric population in case the simulations analyses and results of the clinical study 2 demonstrate that the current ratio vibostolimab / pembrolizumab (5:1) is not appropriate in children from 3 years of age to less than 12 years of age or a body weight $\leq 40$ kg.
Non-clinical studies	Not applicable

Clinical studies	<p><b>Study 2</b></p> <p>Open-label, single-arm, multicentre study to evaluate the safety, pharmacokinetics (part 1-run-in phase) and anti-tumour activity (part 2-expansion phase) of vibostolimab / pembrolizumab in paediatric patients from 3 years to less than 18 years of age with relapsed or refractory classical Hodgkin lymphoma.</p> <p><b>Study 3</b></p> <p>Randomised, active-controlled, multicentre study to evaluate the safety, pharmacokinetics and efficacy of vibostolimab / pembrolizumab used in monotherapy or in combination with standard of care compared to standard of care in paediatric patients from 3 years to less than 18 years of age with newly-diagnosed classical Hodgkin lymphoma. Study design and study population to be agreed by the PDCO based on the results of study 2 prior to study initiation.</p>
Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	Study 2 is part of an extrapolation plan covering the paediatric population with relapsed or refractory classical Hodgkin lymphoma from 3 years to less than 18 years of age, as agreed by the PDCO.

### 3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By April 2034
Deferral for one or more measures contained in the paediatric investigation plan:	Yes



## **Annex II**

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

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

**The product is not authorised anywhere in the European Community.**