

EMA/469858/2023

## European Medicines Agency decision P/0429/2023

of 27 October 2023

on the granting of a product specific waiver for humanised IgG1 monoclonal antibody against TROP2, conjugated to a topoisomerase I inhibitor belotecan-derivative, (EMEA-003461-PIP01-23) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**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 26 May 2023 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 September 2023 in accordance with Article 13 of Regulation (EC) No 1901/2006,

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

Whereas:

- (1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.
- (2) It is therefore appropriate to adopt a decision granting a waiver.

Has adopted this decision:

## **Article 1**

A waiver for humanised IgG1 monoclonal antibody against TROP2, conjugated to a topoisomerase I inhibitor belotecan-derivative, powder for 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 2**

This decision is addressed to Merck Sharp & Dohme (Europe) Inc., Vorstlaan 25, 1170 - Watermaal-Bosvoorde, Belgium.

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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.

EMA/PDCO/264675/2023  
Amsterdam, 8 September 2023

## Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMA-003461-PIP01-23

### Scope of the application

#### Active substance(s):

Humanised IgG1 monoclonal antibody against TROP2, conjugated to a topoisomerase I inhibitor belotecan-derivative

#### Invented name and authorisation status:

See Annex II

#### Condition(s):

Treatment of gastric cancer

Treatment of cervical cancer

Treatment of lung cancer

Treatment of breast cancer

Treatment of ovarian cancer

Treatment of endometrial cancer

#### Pharmaceutical form(s):

Powder for 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 13 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe) Inc. submitted to the European Medicines Agency on 26 May 2023 an application for a product-specific

waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 10 July 2023.

## **Opinion**

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to grant a product-specific waiver for all subsets of the paediatric population and all the above mentioned condition(s) 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 occurs only in adult populations.

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

The grounds for the granting of the waiver are set out in 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**

### **Grounds for the granting of the waiver**

# 1. Waiver

## 1.1. Condition:

Treatment of gastric cancer

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- powder for concentrate for solution for infusion, intravenous 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.

## 1.2. Condition:

Treatment of cervical cancer

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- powder for concentrate for solution for infusion, intravenous 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.

## 1.3. Condition:

Treatment of lung cancer

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- powder for concentrate for solution for infusion, intravenous 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.

## 1.4. Condition:

Treatment of breast cancer

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- powder for concentrate for solution for infusion, intravenous 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.

## 1.5. Condition:

Treatment of ovarian cancer

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- powder for concentrate for solution for infusion, intravenous 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.

### **1.6. Condition:**

Treatment of endometrial cancer

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- powder for concentrate for solution for infusion, intravenous 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.

## **Annex II**

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



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

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