



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/139618/2024

European Medicines Agency decision

P/0100/2024

of 5 April 2024

on the granting of a product-specific waiver for raludotatug deruxtecan (EMEA-003569-PIP01-23) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.



European Medicines Agency decision

P/0100/2024

of 5 April 2024

on the granting of a product-specific waiver for raludotatug deruxtecan (EMA-003569-PIP01-23) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Daiichi Sankyo Europe GmbH on 18 December 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 22 March 2024 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 raludotatug deruxtecan, 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 Daiichi Sankyo Europe GmbH, Zielstattstrasse 48, 81379 – Munich, Germany.

¹ OJ L 378, 27.12.2006, p.1, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/9305/2024
Amsterdam, 22 March 2024

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

EMA-003569-PIP01-23

Scope of the application

Active substance(s):

Raludotatug deruxtecan

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of ovarian cancer

Treatment of fallopian tube cancer

Treatment of primary peritoneal cancer

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Daiichi Sankyo Europe GmbH

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Daiichi Sankyo Europe GmbH submitted to the European Medicines Agency on 18 December 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 22 January 2024.



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 does not occur in the specified subset(s) of the paediatric population,
 - 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 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 ovarian cancer

The waiver applies to:

- all boys from birth to less than 18 years of age and girls from birth to less than 13 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(s).

The waiver applies to:

- all girls from 13 to less than 18 years of age;
- powder for concentrate for solution for infusion, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Waiver

2.1. Condition:

Treatment of fallopian tube 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(s).

3. Waiver

3.1. Condition:

Treatment of primary peritoneal 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(s).

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.