MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver

MHRA-101523-PIP01-24

Scope of the Application

Active Substance(s)

Raludotatug deruxtecan

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 UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Daiichi Sankyo UK Limited submitted to the licensing authority on 25/06/2024 09:52 BST an application for a Waiver

The procedure started on 04/10/2024 14:37 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to grant a product specific waiver.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101523-PIP01-24

Of 14/10/2024 11:39 BST

On the adopted decision for Raludotatug deruxtecan (MHRA-101523-PIP01-24) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a Waiver for Raludotatug deruxtecan, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Daiichi Sankyo UK Limited, Building 4, Uxbridge Business Park Sanderson Road,, Uxbridge, UNITED KINGDOM, UB8 1DH

ANNEX I

1. Waiver

1.1 Condition:

Treatment of ovarian cancer. The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): Powder for concentrate for solution for infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: All boys from birth to less than 18 years of age and girls from birth to less than 13 years of age, 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). All girls from 13 years of age to less than 18 years of age, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments. 1.2 Condition: Treatment of fallopian tube cancer. The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): Powder for concentrate for solution for infusion. Route(s) of administration: INTRAVENOUS USE. Reason for granting waiver: 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). 1.3 Condition: Treatment of primary peritoneal cancer. The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): Powder for concentrate for solution for infusion. Route(s) of administration: INTRAVENOUS USE. Reason

for granting waiver: 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(s):

Not applicable.

2.2 Indication(s) targeted by the PIP:

Not applicable.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

Not applicable.

2.4 Pharmaceutical Form(s):

Not applicable.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	