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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver

MHRA-102318-PIP01-26

Scope of the Application

Active Substance(s)

Taletrectinib adipate

Condition(s)

Treatment of non-small cell lung cancer

Pharmaceutical Form(s)

All pharmaceutical forms

Route(s) of Administration

ALL ROUTES OF ADMINISTRATION

Name / Corporate name of the PIP applicant

Eisai Europe Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Eisai Europe Limited submitted to the licensing authority on 20/02/2026 09:54 GMT an application for a Waiver

The procedure started on 24/02/2026 18:57 GMT

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-102318-PIP01-26

Of 04/03/2026 09:24 GMT

On the adopted decision for Taletrectinib adipate (MHRA-102318-PIP01-26) in accordance with the Human Medicines Regulations 2012.

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

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan).

This decision applies to a Waiver for Taletrectinib adipate, All pharmaceutical forms , ALL ROUTES OF ADMINISTRATION .

This decision is addressed to Eisai Europe Limited, EMEA Knowledge Centre, Mosquito Way, Hatfield, UNITED KINGDOM, AL10 9SN

ANNEX I

1. Waiver

1.1 Condition:

Treatment of non-small cell lung cancer. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): All pharmaceutical forms Route(s) of administration: ALL ROUTES OF ADMINISTRATION 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:	