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

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

confirm the applicability of the Class Waiver.

MHRA-102499-PIP01-26

# Scope of the Application

## Active Substance(s)

etalanetug

## Condition(s)

Treatment of Alzheimer's Disease

## Pharmaceutical Form(s)

Solution for injection/infusion

## Route(s) of Administration

INTRAVENOUS USE

## 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 30/04/2026 11:33 BST an application for a Waiver

The procedure started on 04/06/2026 16:36 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 confirm the applicability of the Class 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-102499-PIP01-26

Of 09/06/2026 18:57 BST

On the adopted decision for etalanetug (MHRA-102499-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:

Confirmation of the applicability of the Class Waiver for the listed condition(s).

This decision applies to a Waiver for etalanetug, Solution for injection/infusion , INTRAVENOUS USE .

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

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Treatment of Alzheimer's Disease. 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): Solution for injection/infusion. Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: the product belongs to ‘all classes of medicinal products for treatment of Alzheimer’s disease’ as stated in Annex II of the adopted Class Waiver Decision CW/0001/2025. |

### 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:** | |