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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100217-PIP01-21-M01

Scope of the Application

Active Substance(s)

ERIBULIN

Condition(s)

Treatment of soft tissue sarcoma

Pharmaceutical Form(s)

Solution for injection

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 25/11/2021 13:56 GMT an application for a Modification

The procedure started on 21/02/2022 10:25 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 accept change(s) to the agreed paediatric investigation plan and to the deferral

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-100217-PIP01-21-M01

Of 11/03/2022 15:06 GMT

On the adopted decision for ERIBULIN (MHRA-100217-PIP01-21-M01) 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 Modification for ERIBULIN, Solution for injection , 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 soft tissue sarcoma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Intravenous use Reason for granting waiver: on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of soft tissue sarcoma

2.2 Indication(s) targeted by the PIP:

Treatment of rhabdomyosarcoma; Treatment of non-rhabdomyosarcoma soft tissue sarcoma; Treatment of Ewing sarcoma

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

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	4	Study 1 (PPC-2012-02n) In vitro sensitivity of 23 human paediatric tumour cell lines to inhibition of proliferation by eribulin Study 2 (PPC-2012-02n) Antitumor activity of eribulin in human paediatric tumour xenografts in athymic mice Study 3 (PPTP Stage 2) Dose-response and Ewing sarcoma testing Study 4 Human RMS tumour xenograft study with eribulin plus irinotecan
Clinical Studies	3	Study 5 (E7389-A001-113) Dose escalation study to assess maximum tolerated dose (MTD), safety and tolerability of eribulin in paediatric patients at least 6 months of age with soft tissue sarcoma Study 6 (E7389-G000-213) Open-label, single arm study to assess safety and efficacy of eribulin in combination with irinotecan in paediatric patients at least 6 months of age with relapsed/refractory soft tissue sarcoma Study 7 (E7389-G000-214) removed in Procedure MHRA-100217-PIP01-M01. Study 8 (E7389-G000-223) (study added in procedure EMEA-001261-PIP01-11-M05) Open-label, uncontrolled, multicentre trial to evaluate safety and preliminary activity of eribulin in children from 12 months to less than 18 years of age with relapsed/

		refractory rhabdomyosarcoma (RMS), nonrhabdomyosarcoma.
Extrapolation, Modeling & Simulation Studies	0	Not applicable
Other Studies	0	Not applicable
Other Measures	0	Not applicable

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

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	30/09/2021
Deferral of one or more studies contained in the paediatric investigation plan:	Yes