

EMA/18866/2021

European Medicines Agency decision

P/0040/2021

of 27 January 2021

on the acceptance of a modification of an agreed paediatric investigation plan for eribulin (Halaven) (EMA-001261-PIP01-11-M06) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/0023/2013 issued on 25 February 2013, the decision P/0109/2014 issued on 5 May 2014, the decision P/0136/2015 issued on 15 June 2015, the decision P/0330/2016 issued on 2 December 2016 and the decision P/0264/2018 issued on 15 August 2018,

Having regard to the application submitted by Eisai GmbH on 11 September 2020 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 December 2020, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for eribulin (Halaven), solution for injection, intravenous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Eisai GmbH, Edmund-Rumpler-Straße 3, 60549 - Frankfurt am Main, Germany.

EMA/PDCO/495393/2020
Amsterdam, 11 December 2020

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001261-PIP01-11-M06

Scope of the application

Active substance(s):

Eribulin

Invented name:

Halaven

Condition(s):

Treatment of soft tissue sarcoma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Eisai GmbH

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eisai GmbH submitted to the European Medicines Agency on 11 September 2020 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0023/2013 issued on 25 February 2013, the decision P/0109/2014 issued on 5 May 2014, the decision P/0136/2015 issued on 15 June 2015, the decision P/0330/2016 issued on 2 December 2016, and the decision P/0264/2018 issued on 15 August 2018.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 13 October 2020.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
 - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

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

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable

2. Paediatric Investigation Plan

2.1. Condition

Treatment of soft tissue sarcoma

2.1.1. Indication(s) targeted by the PIP

Treatment of rhabdomyosarcoma

Treatment of non-rhabdomyosarcoma soft tissue sarcoma

Treatment of Ewing sarcoma

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related measures	0	Not applicable
Non-clinical measures	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 measures	4	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) Randomised, controlled study to compared 2 chemotherapy regimen in newly diagnosed patients with rhabdomyosarcoma from birth to less than 18 years of age 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), non-rhabdomyosarcoma soft tissue sarcoma (NRSTS) and Ewing sarcoma (EWS)
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3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By November 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of breast cancer

Authorised indication(s):

- Treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments.

2. Treatment of soft tissue sarcoma

Authorised indication(s):

- Treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease.

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Intravenous use