20 April 2022
EMA/226690/2022
Human Medicines Evaluation Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Halaven/ eribulin	
Pharmaceutical form(s):	See Annex A
Strength(s):	See Annex A
Route(s) of administration:	See Annex A
Packaging and package size(s):	See Annex A
Number(s) in the Community Register of Medicinal Products:	See Annex A

Marketing authorisation holder (MAH):	
Name and address of the MAH:	Eisai GmbH Edmund-Rumpler-Strasse 3 60549 Frankfurt am Main GERMANY

Procedure	
Procedure number:	EMEA/H/C/002084/IB/0063

Further to the compliance check performed under Article 23 of Regulation (EC) No 1901/2006, and in accordance with Article 28(3) and Article 45(3) of the said Regulation it is concluded that:

- the development of this product has complied with all measures in the agreed paediatric investigation plan P/0535/2021 for the Soft Tissue Sarcoma with the full compliance check procedure EMEA-C-001261-PIP01-11-M07. All studies in the agreed paediatric investigation plan P/00535/2021 were conducted after the entry into force of that Regulation,

- the Summary of Product Characteristics adopted by CHMP already reflected the results of studies conducted in compliance with this agreed paediatric investigation plan.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union