Statement indicating compliance with the agreed completed paediatric investigation plan

9 November 2023

Medicinal product	
Spexotras/ trametinib	
Pharmaceutical form(s):	See Annex A of the CHMP Opinion
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:	Novartis Europharm Limited Vista Building Elm Park Merrion Road Dublin 4 D04 A9N6 IRELAND

Procedure	
Procedure number:	EMEA/H/C/005886/0000

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/0424/2020. All studies in the agreed paediatric investigation plan P/0424/2020 were conducted after the entry into force of that Regulation and the Summary of Product Characteristics reflects 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

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