Statement indicating compliance with the agreed completed paediatric investigation plan

24 July 2025

Medicinal product	
Voranigo/ vorasidenib	
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:	Les Laboratoires Servier 50 Rue Carnot 92284 Suresnes Cedex FRANCE

Procedure	
Procedure number:	EMEA/H/C/006284/0000

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/0007/2022. All studies in the agreed paediatric investigation plan P/0007/2022 were conducted after the entry into force of that Regulation,
- the Summary of Product Characteristics reflects the results of studies conducted in compliance with this agreed paediatric investigation plan.

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