



26 April 2023  
EMA/190289/2023  
Human Medicines Division

## Statement indicating compliance with the agreed completed paediatric investigation plan

### Medicinal product

OPDIVO/ nivolumab

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:	Bristol-Myers Squibb Pharma EEIG Plaza 254 Blanchardstown Corporate Park 2 Dublin 15 D15 T867 IRELAND
------------------------------	--

### Procedure

Procedure number:	EMA/H/C/003985/II/0125/G
-------------------	--------------------------

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/0432/2020. For the purpose of the application of Article 45(3) of Regulation (EC) No 1901/2006, significant studies in the agreed paediatric investigation plan P/0432/2020 were completed 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.

In accordance with Article 23a of Regulation (EC) No 1234/2008, this statement indicating compliance with the agreed completed paediatric investigation plan P/0432/2020 is included in the technical dossier.

