



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Amsterdam, 21 May 2026
EMADOC-1700519818-3098633
PIP compliance
EMA/X/0000296489

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product

Iclusig	
ponatinib	
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:	Incyte Biosciences Distribution B.V. Paasheuvelweg 25 1105 BP Amsterdam Noord-Holland Netherlands
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Procedure

Procedure number:	EMA/X/0000296489
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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 EMA/PE/0000266809. All studies in the agreed paediatric investigation plan EMA/PE/0000266809 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.

In accordance with Article 23a of Regulation (EC) No 1234/2008, this statement indicating compliance with the agreed completed paediatric investigation plan EMA/PE/0000266809 is included in the technical dossier.

