EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 September 2023
EMA/CHMP/424426/2023
Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
TAKHZYRO/ lanadelumab	
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:	Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza 50-58 Baggot Street Lower Dublin D02 HW68 IRELAND

Procedure	
Procedure number:	EMEA/H/C/004806/X/0034/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/0214/2022. All studies in the agreed paediatric investigation plan P/0214/2022 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.