25 April 2024
EMA/182502/2024
Human Medicines Division

# Statement indicating compliance with the agreed completed paediatric investigation plan

| Medicinal product | |
|---|---|
| Beyfortus | |
| International non-proprietary name: nirsevimab | |
| 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: | Sanofi Winthrop Industrie<br>82 Avenue Raspail<br>94250 Gentilly<br>FRANCE |

| Procedure | |
|---|---|
| Procedure number: | EMEA/H/C/005304/II/0018/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/0243/2022. All studies in the agreed paediatric investigation plan P/0243/2022 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.

In accordance with Article 23a of Regulation (EC) No 1234/2008, this statement indicating compliance with the agreed completed paediatric investigation plan P/0243/2022 is included in the technical dossier.