EMA/602323/2022

European Medicines Agency decision

P/0243/2022

of 8 July 2022

on the acceptance of a modification of an agreed paediatric investigation plan for nirsevimab (EMEA-001784-PIP01-15-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0141/2016 issued on 20 May 2016, decision P/0305/2019 issued on 10 September 2019, decision P/0082/2020 issued on 18 March 2020, and decision P/0296/2021 issued on 11 August 2021,

Having regard to the application submitted by AstraZeneca AB on 21 February 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 20 May 2022, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for nirsevimab, solution for injection, intramuscular use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to AstraZeneca AB, SE-151 85 – Södertälje, Sweden.

EMA/PDCO/117506/2022
Amsterdam, 20 May 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001784-PIP01-15-M04

Scope of the application

Active substance(s):

Nirsevimab

Condition(s):

Prevention of lower respiratory tract infection caused by respiratory syncytial virus

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 21 February 2022 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0141/2016 issued on 20 May 2016, the decision P/0305/2019 issued on 10 September 2019, the decision P/0082/2020 issued on 18 March 2020 and the decision P/0296/2021 issued on 11 August 2021.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 21 March 2022.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Prevention of lower respiratory tract infection caused by respiratory syncytial virus

The waiver applies to:

- the paediatric population from 2 years to less than 18 years of age;
- solution for injection, intramuscular use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Prevention of lower respiratory tract infection caused by respiratory syncytial virus

2.1.1. Indication(s) targeted by the PIP

Prevention of lower respiratory tract infection caused by respiratory syncytial virus (RSV) in all infants entering their first RSV season and children with Chronic Lung Disease or Congenital Heart Disease entering their first and second RSV season

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 2 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (D5290C00002)** Randomized, double-blind, placebo-controlled, single ascending dose study to evaluate pharmacokinetic (PK) and safety of MEDI8897 in preterm infants less than or equal to 35 weeks gestation and less than 12 months of chronological age, not eligible for palivizumab prophylaxis

	Study 2 (D5290C00003) Randomized, double-blind, placebo-controlled, single-dose efficacy and safety study in healthy preterm infants less than or equal to 35 weeks gestation and less than or equal to 8 months of chronological age, not eligible for palivizumab prophylaxis **Study 3 (D5290C00004)** Randomized, double-blind, placebo controlled, single-dose efficacy and safety study in healthy infants of greater than 35 weeks gestational age and less than or equal to 8 months of chronological age, including infants with a chronic underlying illness who are healthy at the time of enrolment (MELODY) **Study 4 (D5290C00005)** Double-blind, palivizumab controlled, safety and PK bridging study with collection of efficacy data for trend toward efficacy in preterm infants who are eligible to receive palivizumab in their first RSV season or infants with chronic lung disease (CLD) or congenital heart disease (CHD) less than 2 years of age in their first and second RSV season (MEDLEY)
Extrapolation, modelling and simulation studies	**Study 5** Modelling and simulation study to optimise appropriate intramuscular dose regimens that will result in a protective concentration against RSV during the dose interval and the remaining of the RSV season in infants and children less than or equal to 24 months of age at the start of the RSV season **Study 6** Extrapolation study to assess whether the efficacy of MEDI8897 from study 2 in preterm infants and from study 3 in term infants entering their first RSV season applies to the palivizumab eligible population
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes