EMA/434365/2021

European Medicines Agency decision

P/0296/2021

of 11 August 2021

on the acceptance of a modification of an agreed paediatric investigation plan for anti-respiratory syncytial virus human IgG1κ monoclonal antibody (MEDI8897) (EMEA-001784-PIP01-15-M03) 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.

European Medicines Agency decision

P/0296/2021

of 11 August 2021

on the acceptance of a modification of an agreed paediatric investigation plan for anti-respiratory syncytial virus human IgG1κ monoclonal antibody (MEDI8897) (EMEA-001784-PIP01-15-M03) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary 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, and decision P/0082/2020 issued on 18 March 2020,

Having regard to the application submitted by AstraZeneca AB on 22 March 2021 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 25 June 2021, 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 and to the deferral.

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

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for anti-respiratory syncytial virus human IgG1κ monoclonal antibody (MEDI8897), solution for injection, intramuscular use, including changes to the deferral, 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, Forskargatan 18, SE-151 85- Södertälje, Sweden.

EMA/PDCO/214476/2021
Amsterdam, 25 June 2021

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

EMEA-001784-PIP01-15-M03

Scope of the application

Active substance(s):

Anti-respiratory syncytial virus human IgG1κ monoclonal antibody (MEDI8897)

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 22 March 2021 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, decision P/0305/2019 issued on 10 September 2019, and decision P/0082/2020 issued on 18 March 2020.

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

The procedure started on 27 April 2021.

Scope of the modification

Some measures and 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 and to the deferral in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member 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;
- 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	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	4	**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	2	**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	0	Not applicable
Other measures	0	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