EMA/300113/2021

European Medicines Agency decision

P/0236/2021

of 8 June 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral for tixagevimab (AZD8895) (EMEA-002900-PIP01-20) 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 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 application submitted by AstraZeneca AB on 27 November 2020 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 April 2021, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a 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

A paediatric investigation plan for tixagevimab (AZD8895), solution for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for tixagevimab (AZD8895), solution for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to AstraZeneca AB, Forskargatan 18, SE-151 85 – Södertälje, Sweden.

EMA/PDCO/198578/2021
Amsterdam, 21 May 2021

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-002900-PIP01-20

Scope of the application

Active substance(s):

Tixagevimab (AZD8895)

Condition(s):

Treatment of Coronavirus disease 2019 (COVID-19)

Prevention of Coronavirus disease 2019 (COVID-19)

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 16(1) of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted for agreement to the European Medicines Agency on 27 November 2020 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 4 January 2021.

Supplementary information was provided by the applicant on 12 March 2021. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

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

2. The measures and timelines of the agreed paediatric investigation plan 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of Coronavirus disease 2019 (COVID-19)

Prevention of Coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients with Coronavirus disease 2019 (COVID-19) who are at risk of progressing to severe disease.

Pre- and post-exposure prophylaxis of Coronavirus disease 2019 (COVID-19) in children who are at risk of developing severe disease.

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

From birth to less than 18 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	1	**Study 1** Open label, uncontrolled, single dose study to evaluate the pharmacokinetics (PK), pharmacodynamics (PD) and safety of tixagevimab and cilgavimab for the treatment of paediatric patients with mild to moderate COVID-19 at high risk for developing severe disease and for pre and post- exposure prophylaxis in paediatric subjects from 29 weeks gestational age (GA) to less than 18 years of age at high risk of developing severe COVID-19.

Extrapolation, modelling and simulation studies	3	**Study 2** Two-compartment population PK (PopPK) model for tixagevimab and cilgavimab dosing prediction and confirmation in paediatric patients from 29 weeks of gestational age (GA) to less than 18 years of age. **Study 3** PK bridging and extrapolation of clinical efficacy and safety of tixagevimab and cilgavimab for pre- and post-exposure prophylaxis of COVID-19 in adults at risk of developing severe disease to efficacy and safety for pre- and post-exposure prophylaxis of COVID-19 in paediatric populations from 29 weeks gestational age to less than 18 years of age at risk of developing severe disease. **Study 4** PK bridging and extrapolation of clinical efficacy and safety of tixagevimab and cilgavimab for treatment of mild-moderate COVID-19 in adult patients at risk of developing severe disease to efficacy and safety for treatment of mild-moderate COVID-19 in paediatric patients from 29 weeks gestational age to less than 18 years of age at risk of developing severe disease.
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:	No
Date of completion of the paediatric investigation plan:	By June 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes