EMA/526329/2023

European Medicines Agency decision

P/0460/2023

of 1 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for cilgavimab (Evusheld), (EMEA-002925-PIP01-20-M02) 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/0235/2021 issued on 8 June 2021 and the decision P/0048/2022 issued on 11 February 2022,

Having regard to the application submitted by Astrazeneca AB on 21 June 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 October 2023, in accordance with Article 22 of Regulation (EC) No 1901/2006 and of its own motion in accordance with Article 12 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 acceptance of changes to the agreed paediatric investigation plan and on the granting of a waiver.

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

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

[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 cilgavimab (Evusheld), solution for injection/infusion, intramuscular use, intravenous 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

A waiver for cilgavimab (Evusheld), solution for injection/infusion, intramuscular use, intravenous use, the details of which are set out in the opinion of the Paediatric Committee 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/317024/2023
Amsterdam, 13 October 2023

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

EMEA-002925-PIP01-20-M02

Scope of the application

Active substance(s):

Cilgavimab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of coronavirus disease 2019 (COVID-19)

Prevention of coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Solution for injection/infusion

Route(s) of administration:

Intramuscular use

Intravenous 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 June 2023 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0235/2021 issued on 8 June 2021 and the decision P/0048/2022 issued on 11 February 2022.

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

The procedure started on 14 August 2023.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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;
   - to grant a waiver for one or more subsets of the paediatric population of its own motion in accordance with Article 12 of said Regulation and concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 annexes 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:

Treatment of coronavirus disease 2019 (COVID-19)

The waiver applies to:

- the paediatric population from birth to less than 12 years of age;
- solution for injection/infusion; intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

1.2. Condition

Prevention of coronavirus disease 2019 (COVID-19)

The waiver applies to:

- the paediatric population from birth to less than 12 years of age;
- solution for injection/infusion; intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric investigation plan

2.1. Condition:

Treatment 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

Treatment of paediatric patients with severe Coronavirus disease 2019 (COVID-19)

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

From 12 years of age to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection/infusion

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	**Study 1 (D8850C00006)** Open label, uncontrolled, single dose study to evaluate pharmacokinetics (PK), pharmacodynamics (PD) and safety of tixagevimab and cilgavimab in children from 12 years of age to less than 18 years of age for: • pre-exposure prophylaxis of COVID-19 in children at high risk of developing severe disease (Cohort 1) • treatment of mild to moderate COVID-19 in children at high risk for developing severe disease (Cohort 2) • treatment of severe COVID-19 (Cohort 3) *This study is the same as study 1 in condition Prevention of coronavirus disease 2019 (COVID-19).*
Extrapolation, modelling and simulation studies	**Study 2** *Study deleted with procedure EMEA-002925-PIP01-20-M02* **Study 3** *Study deleted with procedure EMEA-002925-PIP01-20-M02* **Study 4** *Study deleted within procedure EMEA-002900-PIP01-20-M01.*
Other studies	Not applicable.
Other measures	Not applicable.

2.2. Conditions

Prevention of Coronavirus disease 2019 (COVID-19)

2.2.1. Indication(s) targeted by the PIP

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

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

From 12 years of age to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Solution for injection/infusion

2.2.4. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	**Study 1 (D8850C00006)** Open label, uncontrolled, single dose study to evaluate pharmacokinetics (PK), pharmacodynamics (PD) and safety of tixagevimab and cilgavimab in children from 12 years of age to less than 18 years of age for: • pre-exposure prophylaxis of COVID-19 in children at high risk of developing severe disease (Cohort 1) • treatment of mild to moderate COVID-19 in children at high risk for developing severe disease (Cohort 2) • treatment of severe COVID-19 (Cohort 3) *This study is the same as study 1 in condition Treatment of coronavirus disease 2019 (COVID-19)*
Extrapolation, modelling and simulation studies	**Study 2** *Study deleted with procedure EMEA-002925-PIP01-20-M02* **Study 3** *Study deleted with procedure EMEA-002925-PIP01-20-M02* **Study 4** *Study deleted within procedure EMEA-002900-PIP01-20-M01.*
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:	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

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Prevention of COVID-19

Authorised indication(s):

- Pre-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg
  - Invented name(s): Evusheld
  - Authorised pharmaceutical form(s): Solution for injection/infusion
  - Authorised route(s) of administration: intramuscular route
  - Authorised via centralised procedure

2. Treatment of COVID-19

- Treatment of adults and adolescents (aged 12 years and older weighing at least 40 kg) with COVID-19, who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19
  - Invented name(s): Evusheld
  - Authorised pharmaceutical form(s): Solution for injection/infusion
  - Authorised route(s) of administration: intramuscular route
  - Authorised via centralised procedure