



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/148128/2024

European Medicines Agency decision P/0144/2024

of 6 May 2024

on the agreement of a paediatric investigation plan and on the granting of a deferral for tozorakimab (EMA-003360-PIP01-22) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by AstraZeneca AB on 18 November 2022 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 22 March 2024, 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, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for tozorakimab, solution for injection, intravenous 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 tozorakimab, solution for injection, intravenous 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, Södertälje, SE-151 85 – Södertälje, Sweden.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/6848/2024 Corr¹
Amsterdam, 22 March 2024

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

EMA-003360-PIP01-22

Scope of the application

Active substance(s):

Tozorakimab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of severe viral lower respiratory tract disease

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous 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 18 November 2022 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 3 January 2023.

Supplementary information was provided by the applicant on 15 December 2023.

¹ 25 April 2024.



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 Paediatric Committee member of Norway 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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of severe viral lower respiratory tract disease.

2.1.1. Indication(s) targeted by the PIP

Treatment of severe viral lower respiratory tract 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	Description
Quality-related studies	Study 1 Development of an age-appropriate lower dose strength solution for injection, intravenous use, for the paediatric population from birth to less than 2 years of age.
Non-clinical studies	Study 2 Enhanced pre- and postnatal development study To assess potential maternal and developmental effects of tozorakimab, and to evaluate growth and development of infants for 6 months postnatally after administration of tozorakimab to birth mothers during gestation.
Clinical studies	Study 3 Open-label, 2-part, single-dose, single-arm trial to evaluate the pharmacokinetics and safety of tozorakimab as add-on to standard of care in children from birth to less than 18 years of age, hospitalised with suspected viral lower respiratory tract disease requiring supplemental oxygen. Study 4 Double-blind, randomised, single dose, parallel arm, placebo-controlled trial to evaluate efficacy and safety of tozorakimab in children from birth to less than 2 years of age hospitalised with suspected or confirmed viral lower respiratory tract disease requiring supplemental oxygen.

	<p>Study 5</p> <p>Clinical study to evaluate the safety, efficacy, pharmacokinetics (PK), pharmacodynamics (PD) and immunogenicity of tozorakimab in children from 2 years to less than 18 years of age hospitalised with suspected or confirmed viral lower respiratory tract disease (LRTD) requiring supplemental oxygen.</p>
Modelling and simulation analyses	<p>Study 6 (Population Pharmacokinetic model)</p> <p>To define doses and sample size for PIP study 3 and to define doses for PIP studies 4 and 5.</p> <p>Study 7 (Population Pharmacokinetic/ Pharmacodynamic Model)</p> <p>PopPK/PD model with efficacy and or PD data from Phase 3 in adults and available data from paediatric population (PIP studies 3, 4 and 5), to assist with the extrapolation of efficacy from adults and from paediatric patients from birth to less than 2 years of age to the paediatric population from 2 years of age to less than 18 years of age.</p>
Other studies	Not applicable.
Extrapolation plan	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 2032
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:

The product is not authorised anywhere in the European Community.