EMADOC-1700519818-2008462

European Medicines Agency decision

EMA/PE/0000240018

of 16 April 2025

on the acceptance of a modification of an agreed paediatric investigation plan for tezepelumab (Tezspire) 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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on the acceptance of a modification of an agreed paediatric investigation plan for Tezepelumab (Tezspire) 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 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/0316/2014 issued on 5 December 2014, the decision P/0365/2018 issued on 7 December 2018, the decision P/0263/2019 issued on 19 July 2019 and the decision P/0012/2020 issued on 6 January 2020,

Having regard to the application submitted by AstraZeneca AB on 16 December 2024 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 28 February 2025, 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 tezepelumab, 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, 151 85 Sodertalje, Sweden.

EMADOC-1700519818-1853527
Amsterdam, 28 February 2025

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

EMA/PE/0000240018

Scope of the application

Active substance(s):

Tezepelumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous 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 16 December 2024 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/0316/2014 issued on 5 December 2014, the decision P/0365/2018 issued on 7 December 2018, the decision P/0263/2019 issued on 19 July 2019 and the decision P/0012/2020 issued on 6 January 2020.

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

The procedure started on 27 January 2025.

Scope of the modification

Some measures or 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 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 asthma

The waiver applies to:

- the paediatric population from birth to less than 5 years;
- solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition

Treatment of asthma

2.1.1. Indication(s) targeted by the PIP

Reduction of the frequency of asthma exacerbations in children and adolescent patients (5 to 17 years) with uncontrolled asthma despite the daily use of controller medications described in Step 4 or Step 5 of the Global Initiative for Asthma (GINA) Guidelines.

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

From 5 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	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** Open-label, single-dose study to evaluate the pharmacokinetic (PK) profile of tezepelumab in adolescent subjects 12 to less than 18 years with asthma

	Study 2 Double-blind study to evaluate the efficacy and safety of tezepelumab in adolescents 12 to less than 18 years (and adults) with uncontrolled asthma **Study 3** Deleted during procedure EMEA001613-PIP01-14-M02 **Study 4** Open-label study to evaluate the pharmacokinetic (PK) profile of single dose of tezepelumab 70 mg SC in children aged 5 to 11 years with mild, moderate or severe asthma requiring daily controller medications **Study 5** Double-blind study to evaluate the efficacy and safety of tezepelumab in children 5 to less than 12 years with uncontrolled asthma
Extrapolation, modelling and simulation studies	**Study 6** Modelling and simulation study for selection of dose and dose regimen in children 5 to less than 12 years
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 2028
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. Treatment of asthma

Authorised indication(s):

- Indicated as an add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment.
  - Invented name(s): Tezspire
  - Authorised pharmaceutical form(s): Solution for injection in pre-filled syringe (injection); Solution for injection in pre-filled pen (injection)
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure