

EMA/762217/2018

European Medicines Agency decision

P/0365/2018

of 7 December 2018

on the acceptance of a modification of an agreed paediatric investigation plan for tezepelumab (EMA-001613-PIP01-14-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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0316/2014 issued on 5 December 2014,

Having regard to the application submitted by AstraZeneca AB on 3 July 2018 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 19 October 2018, 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 and to the waiver.
- (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 and to the waiver.

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 tezepelumab, solution for injection, subcutaneous use, including changes to the deferral, and to the waiver, 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, Karlebyhus, SE-151 85 - Södertälje, Sweden.

EMA/PDCO/481690/2018
London, 19 October 2018

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001613-PIP01-14-M02

Scope of the application

Active substance(s):

Tezepelumab

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 3 July 2018 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 application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and to the waiver.

The procedure started on 21 August 2018.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. The subset covered by the waiver has changed.

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 and to the waiver 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

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	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	4	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 Double-blind, placebo-controlled study to evaluate the pharmacokinetic (PK) and pharmacodynamic (PD) profile of single dose of tezepelumab 70 mg SC in children aged 5 to 11 years with uncontrolled severe asthma requiring daily controller medications (Step 4 of the GINA guidelines). 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	1	Study 6 Modelling and simulation study for selection of dose and dose regimen in children 5 to less than 12 years.
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 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes