

EMA/538548/2018

European Medicines Agency decision

P/0300/2018

of 12 September 2018

on the acceptance of a modification of an agreed paediatric investigation plan for mepolizumab (Nucala), (EMA-000069-PIP04-13-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/0326/2014 issued on 22 December 2014 and the decision P/0281/2016 issued on 4 November 2016,

Having regard to the application submitted by GSK Trading Services Limited on 10 April 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 27 July 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.
- (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.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for mepolizumab (Nucala), powder for solution for injection or infusion, solution for injection, subcutaneous 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

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/52/2008 issued on 20 July 2008, including subsequent modifications thereof.

Article 3

This decision is addressed to GSK Trading Services Limited, Currabinny, Carrigaline, Cork, Ireland.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/299616/2018

London, 27 July 2018

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000069-PIP04-13-M02

Scope of the application

Active substance(s):

Mepolizumab

Invented name:

Nucala

Condition(s):

Treatment of vasculitides

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for injection or infusion

Solution for injection

Route(s) of administration:

Subcutaneous use

Name / corporate name of the PIP applicant:

GSK Trading Services Limited

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GSK Trading Services Limited submitted to the European Medicines Agency on 10 April 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/0326/2014 issued on 22 December 2014 and the decision P/0281/2016 issued on 4 November 2016.

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

The procedure started on 29 May 2018.

Scope of the modification

Some measures 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 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 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 vasculitides

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- powder for solution for injection or infusion, solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric investigation plan

2.1. Condition

Treatment of vasculitides

2.1.1. Indication(s) targeted by the PIP

Treatment of eosinophilic granulomatosis with polyangiitis

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

From 6 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for solution for injection or infusion

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	0	Not applicable.

Extrapolation, modelling and simulation studies	4	Study 1: Modelling and simulation study to predict the PK of mepolizumab in the treatment of adult with eosinophilic granulomatosis with polyangiitis. Study 2 Modelling and simulation study to demonstrate the PK and PKPD in children (6-17 years) prediction from adults with severe asthma and eosinophilic granulomatosis with polyangiitis. Study 3 Modelling and simulation study to demonstrate the efficacy (exacerbation) observed in adolescents (12-17 years) with severe asthma is comparable to that observed in adults with severe asthma at similar exposure. Study 4 Extrapolation study to evaluate PK and blood eosinophil count to the EGPA paediatric population (6-17 years) based on data from adults with EGPA and severe asthma and data from children with severe asthma (12-17 years) and EE (2-17 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:	No
Date of completion of the paediatric investigation plan:	By September 2018
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of severe asthma

Authorised indication(s):

- Nucala is indicated as an add-on treatment for severe refractory eosinophilic asthma in adult patients

Authorised pharmaceutical form(s):

Powder for solution for injection

Authorised route(s) of administration:

Subcutaneous use