EMA/704428/2016

European Medicines Agency decision

P/0281/2016

of 4 November 2016

on the acceptance of a modification of an agreed paediatric investigation plan for mepolizumab (Nucala), (EMEA-000069-PIP04-13-M01) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0326/2014 issued on 22 December 2014,

Having regard to the application submitted by GSK Trading Services Limited on 27 June 2016 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 September 2016, in accordance with Article 22 of Regulation (EC) No 1901/2006 and of its own motion in accordance with 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 acceptance of changes to the agreed paediatric investigation plan and on the granting of a deferral.

(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 on the granting of a deferral.

[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, 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

A deferral for mepolizumab (Nucala), powder for solution for injection or infusion, subcutaneous 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 GSK Trading Services Limited, Currabinny, Carrigaline, County Cork , Cork- Ireland.

EMA/PDCO/456657/2016 Corr
London, 16 September 2016

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

EMEA-000069-PIP04-13-M01

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

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

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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 27 June 2016 an application for modification of the agreed paediatric investigation plan and a waiver as set out in the European Medicines Agency's decision P/0326/2014 issued on 22 December 2014.

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

The procedure started on 19 July 2016.

Scope of the modification

Some measures and 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;

   and in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended, recommends:

   - to grant a deferral on its own motion in accordance with Article 21 of said Regulation.

   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, 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

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies		Not applicable.
Non-clinical studies		Not applicable.
Clinical studies		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		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 May 2017
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