EMA/491414/2017

European Medicines Agency decision

P/0239/2017

of 11 August 2017

on the acceptance of a modification of an agreed paediatric investigation plan for mepolizumab (Nucala), (EMEA-000069-PIP02-10-M08) 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

An agency of the European Union

European Medicines Agency decision

P/0239/2017

of 11 August 2017

on the acceptance of a modification of an agreed paediatric investigation plan for mepolizumab (Nucala), (EMEA-000069-PIP02-10-M08) 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 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/219/2011 issued on 26 September 2011, the decision P/0054/2013 issued on 25 March 2013, the decision P/0234/2013 issued on 24 September 2013, the decision P/0161/2014 issued on 12 June 2014, the decision P/0234/2014 issued on 29 August 2014, the decision P/0139/2015 issued on 10 July 2015 and the decision P/0047/2017 issued on 17 March 2017,

Having regard to the application submitted by GlaxoSmithKline Trading Services on 26 May 2017 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 21 July 2017, 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 / infusion, solution for injection, intravenous use, 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 is addressed to GlaxoSmithKline Trading Services, Currabinny, Carrigaline, Cork, Ireland.

EMA/PDCO/353680/2017
London, 21 July 2017

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

EMEA-000069-PIP02-10-M08

Active substance(s):

Mepolizumab

Invented name:

Nucala

Condition(s):

Treatment of asthma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for injection / infusion

Solution for injection

Route(s) of administration:

Intravenous use

Subcutaneous use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Trading Services

Information about the authorised medicinal product:

See Annex II

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
Send a question via our website www.ema.europa.eu/contact

An agency of the European Un on

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services submitted to the European Medicines Agency on 26 May 2017 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/219/2011 issued on 26 September 2011, the decision P/0054/2013 issued on 25 March 2013, the decision P/0234/2013 issued on 24 September 2013, the decision P/0161/2014 issued on 12 June 2014, the decision P/0234/2014 issued on 29 August 2014, the decision P/0139/2015 issued on 10 July 2015 and the decision P/0047/2017 issued on 17 March 2017.

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

The procedure started on 20 June 2017.

Scope of the modification

Amendment of the scope of the Paediatric Investigation Plan to include another pharmaceutical form.

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 asthma

The waiver applies to:

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

2. Paediatric Investigation Plan

2.1. Condition

Treatment of asthma

2.1.1 Indication(s) targeted by the PIP

Reduction of severe asthma exacerbations

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 / infusion

Solution for injection

2.1.4 Measures

Area	Number of studies	Description
Quality-related studies	0	***Study 1*** *Deleted during procedure EMEA-000069-PIP02-10-M02*
Non-clinical studies	0	Not applicable

Clinical studies	5	**Study 2** Double-blind, randomised, multi-centre, placebo-controlled, parallel-group study to evaluate efficacy and safety of mepolizumab as add-on therapy in children from 12 to less than 18 years old (and in adults) with severe uncontrolled asthma(MEA115588) **Study 3** Double-blind, randomised, multi-centre, placebo-controlled, parallel-group study to evaluate efficacy of mepolizumab to reduce steroid use as add-on therapy in children from 12 to less than 18 years old (and in adults) with severe uncontrolled asthma (MEA115575) ***Study 4*** *Deleted during procedure EMEA-000069-PIP02-10-M02* ***Study 5*** *Deleted during procedure EMEA-000069-PIP02-10-M02* **Study 6** Double-blind, randomised, dose ranging, parallel group trial to evaluate PK/PD, safety and tolerability of mepolizumab in children from 2 to less than 18 years of age with eosinophilic esophagitis (MEE103219) **Study 7** Open-label trial to evaluate PK/PD, safety and tolerability of mepolizumab as add-on to best standard of care in children from 6 to less than 12 years of age with severe eosinophilic asthma (200363)
Extrapolation, modelling & simulation studies	0	**Study 8** Analysis of PK, PD, efficacy, safety and tolerability data on mepolizumab from studies 2, 3, 6 and 7 in conditions severe eosinophilic asthma and eosinophilic esophagitis(Extrapolation study)
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 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 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