EMA/487753/2020

European Medicines Agency decision

P/0384/2020

of 23 September 2020

on the acceptance of a modification of an agreed paediatric investigation plan for mepolizumab (Nucala) (EMEA-000069-PIP01-07-M07) 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/52/2008 issued on 20 July 2008, the decision P/94/2009 issued on 19 May 2009, the decision P/164/2010 issued on 31 August 2010, the decision P/0083/2015 issued on 8 May 2015, and the decision P/0007/2016 issued on 29 January 2016,

Having regard to the application submitted by GSK Trading Services Limited on 5 June 2020 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and proposing a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 4 September 2020, in accordance with Article 22 of Regulation (EC) No 1901/2006 and Article 13 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 to the deferral and on the granting of a 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.

(3) It is therefore appropriate to adopt a decision granting a 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 mepolizumab (Nucala), powder for solution for injection, solution for injection in pre-filled syringe, subcutaneous use, including changes to the deferral, 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 waiver for mepolizumab (Nucala), powder for solution for injection, solution for injection in pre-filled syringe, 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, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

EMA/PDCO/325428/2020
Amsterdam, 4 September 2020

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

EMEA-000069-PIP01-07-M07

Scope of the application

Active substance(s):

Mepolizumab

Invented name:

Nucala

Condition(s):

Treatment of hypereosinophilic syndrome

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for injection

Solution for injection in pre-filled syringe

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 5 June 2020 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/52/2008 issued on 20 July 2008, the decision P/94/2009 issued on 19 May 2009, the decision P/164/2010 issued on 31 August 2010, the decision P/0083/2015 issued on 8 May 2015, and the decision P/0007/2016 issued on 29 January 2016.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and proposed a waiver.

The procedure started on 6 July 2020.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a paediatric subset has been added.

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 in the scope set out in the Annex I of this opinion;
   - to grant a waiver for one or more subsets of the paediatric population concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 hypereosinophilic syndrome

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- Powder for solution for injection, solution for injection in pre-filled syringe, 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 hypereosinophilic syndrome

2.1.1. Indication(s) targeted by the PIP

Treatment of hypereosinophilic syndrome

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

Children and adolescents from 6 to less than 18 years

2.1.3. Pharmaceutical form(s)

Powder for solution for injection

Solution for injection in pre-filled syringe

2.1.4. Solution for injection in pre-filled syringeMeasures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	2	**Study 1** Fertility, early embryonic and embryo-fetal development in mice. (RSD 100P8V) **Study 2** Pre - and postnatal development in Cynomolgus monkeys. (CD2003/01020/00)

Clinical studies	1	**Study 3** A 52-week, open-label multi-centre study of the efficacy and safety of mepolizumab administered in children 6 to less than 18 years of age with hypereosinophilic syndrome.
Extrapolation, modelling and simulation studies	3	**Study 4 (added during EMEA-000069-PIP01-07-M07)** Modelling and simulation study, to support the use of mepolizumab in children 6 to less than 18 years of age with hypereosinophilic syndrome. **Study 5 (added during EMEA-000069-PIP01-07-M07)** Modelling prediction study to support the use of mepolizumab in children 6 to less than 18 years of age with hypereosinophilic syndrome. **Study 6 (added during EMEA-000069-PIP01-07-M07)** Extrapolation study, to support the use of mepolizumab in children 6 to less than 18 years of age with hypereosinophilic syndrome.

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 2025
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):

- indicated as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older

Authorised pharmaceutical form(s):

Powder for solution for injection

Solution for injection in pre-filled syringe

Authorised route(s) of administration:

Subcutaneous use