EMA/465524/2024

European Medicines Agency decision

P/0367/2024

of 25 October 2024

on the acceptance of a modification of an agreed paediatric investigation plan for mepolizumab (Nucala), (EMEA-000069-PIP01-07-M09) 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 Union procedures for the authorisation and supervision of medicinal products for human 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, the decision P/0007/2016 issued on 29 January 2016 and the decision P/0384/2020 issued on 23 September 2020,

Having regard to the application submitted by GSK Trading Services Limited on 31 May 2024 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 6 September 2024, 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.

(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.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

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

This decision is addressed to GSK Trading Services Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24 - Dublin 24, Ireland.

EMA/PDCO/278971/2024
Amsterdam, 6 September 2024

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

EMEA-000069-PIP01-07-M09

Scope of the application

Active substance(s):

Mepolizumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of hypereosinophilic syndrome

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

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 31 May 2024 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/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, the decision P/0007/2016 issued on 29 January 2016 and the decision P/0384/2020 issued on 23 September 2020.

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

The procedure started on 8 July 2024.

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 and to the deferral in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway 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. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	**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	**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	**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 October 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of severe eosinophilic asthma

Authorised indication(s):

- Nucala is indicated as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older
  - Invented name(s): Nucala
  - Authorised pharmaceutical form(s):

    100 mg powder for solution for injection

    100 mg solution for injection in pre-filled pen

    100 mg solution for injection in pre-filled syringe

    40 mg solution for injection in pre-filled syringe
  - Authorised route(s) of administration: Subcutaneous
  - Authorised via centralised procedure

2. Treatment of Chronic rhinosinusitis with nasal polyps (CRSwNP)

Authorised indication(s):

- Nucala is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.
  - Invented name(s): Nucala
  - Authorised pharmaceutical form(s):

    100 mg powder for solution for injection

    100 mg solution for injection in pre-filled pen

    100 mg solution for injection in pre-filled syringe
  - Authorised route(s) of administration: Subcutaneous
  - Authorised via centralised procedure

3. Treatment of Eosinophilic granulomatosis with polyangiitis (EGPA)

Authorised indication(s):

- Nucala is indicated as an add-on treatment for patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA).
  - Invented name(s): Nucala
  - Authorised pharmaceutical form(s):

    100 mg powder for solution for injection

    100 mg solution for injection in pre-filled pen

100 mg solution for injection in pre-filled syringe

- Authorised route(s) of administration: Subcutaneous
- Authorised via centralised procedure

4. Treatment of Hypereosinophilic syndrome (HES)

Authorised indication(s):

- Nucala is indicated as an add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable non-haematologic secondary cause
  - Invented name(s): Nucala
  - Authorised pharmaceutical form(s):

    100 mg powder for solution for injection

    100 mg solution for injection in pre-filled pen

    100 mg solution for injection in pre-filled syringe
  - Authorised route(s) of administration: Subcutaneous
  - Authorised via centralised procedure