EMA/517349/2023

European Medicines Agency decision

P/0485/2023

of 1 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for zanamivir (Relenza), (EMEA-001318-PIP01-12-M05) 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/0097/2013 issued on 29 April 2013, the decision P/0094/2015 issued on 8 May 2015, the decision P/0212/2017 issued on 9 August 2017, the decision P/0415/2019 issued on 4 December 2019 and the decision P/0391/2020 issued on 23 October 2020,

Having regard to the application submitted by GlaxoSmithKline Trading Services Limited on 28 June 2023 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 13 October 2023, 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 zanamivir (Relenza), inhalation powder, pre-dispensed, solution for infusion, inhalation use, intravenous 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 GlaxoSmithKline Trading Services Limited, Currabinny, Carrigaline, County Cork, Ireland.

EMA/PDCO/319880/2023
Amsterdam, 13 October 2023

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

EMEA-001318-PIP01-12-M05

Scope of the application

Active substance(s):

Zanamivir

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of influenza

Treatment of influenza

Pharmaceutical form(s):

Inhalation powder, pre-dispensed

Solution for infusion

Route(s) of administration:

Inhalation use

Intravenous use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Trading Services Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted to the European Medicines Agency on 28 June 2023 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/0097/2013 issued on 29 April 2013, the decision P/0094/2015 issued on 8 May 2015, the decision P/0212/2017 issued on 9 August 2017, the decision P/0415/2019 issued on 4 December 2019 and the decision P/0391/2020 issued on 23 October 2020.

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

The procedure started on 14 August 2023.

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 influenza

The waiver applies to:

- all subsets of the paediatric population from birth to less than 5 years of age;
- inhalation powder, pre-dispensed, inhalation use;
- on the grounds that the specific medicinal product is likely to be ineffective.

And to:

- all subsets of the paediatric population from 5 to less than 18 years of age;
- inhalation powder, pre-dispensed, inhalation use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

1.2. Condition:

Prevention of influenza

The waiver applies to:

- all subsets of the paediatric population from birth to less than 5 years of age;
- inhalation powder, pre-dispensed, inhalation use;
- on the grounds that the specific medicinal product is likely to be ineffective.

And to:

- all subsets of the paediatric population from 5 to less than 18 years of age;
- inhalation powder, pre-dispensed, inhalation use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of influenza

2.1.1. Indication(s) targeted by the PIP

Treatment of influenza A and B virus infection

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for infusion

2.1.4. Studies

Area	Description
Quality	Not applicable.
Non-clinical	Not applicable.
Clinical	**Study 1 (NAI 113678)** Open-label, single-arm study to evaluate PK, safety and tolerability of zanamivir in hospitalized children from 6 months to less than 18 years of age with confirmed influenza virus infection. **Study 2** Open-label, single-arm study to evaluate PK, safety and tolerability of zanamivir in hospitalized children from 28 weeks post-menstrual age (PMA) to less than 6 months of age with confirmed influenza virus infection.
Extrapolation, modelling and simulation studies	Not applicable.
Other studies	Not applicable.
Other measures	Not applicable.

2.2. Condition:

Prevention of influenza

2.2.1. Indication(s) targeted by the PIP

Prevention of influenza A and B virus infection

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

From birth to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Solution for infusion

2.2.4. Studies

Area	Description
Quality	Not applicable.
Non-clinical	Not applicable.
Clinical	**Study 3** Extrapolation of efficacy and safety zanamivir IV for the prevention of influenza infection from adult data for prevention (challenge study) and from the treatment of influenza program in children.
Extrapolation, modelling and simulation studies	Not applicable.
Other studies	Not applicable.
Other measures	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2026
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of influenza infection

   Authorised indication(s):

- Relenza is indicated for treatment of both influenza A and B in adults and children (≥ 5 years) who present with symptoms typical of influenza when influenza is circulating in the community.

2. Prevention of influenza infection

   Authorised indication(s):

- Relenza is indicated for post-exposure prophylaxis of influenza A and B in adults and children (≥ 5 years) following contact with a clinically diagnosed case in a household. In exceptional circumstances, Relenza may be considered for seasonal prophylaxis of influenza A and B during a community outbreak (e.g. in case of a mismatch between circulating and vaccine strains and a pandemic situation).

Authorised pharmaceutical form(s):

Inhalation powder, pre-dispensed

Authorised route(s) of administration:

Inhalation use