

EMA/770101/2018

European Medicines Agency decision

P/0344/2018

of 8 November 2018

on the acceptance of a modification of an agreed paediatric investigation plan for fosnetupitant / palonosetron (Akynzeo), (EMA-001198-PIP03-17-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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0140/2018 issued on 7 May 2018,

Having regard to the application submitted by Helsinn Birex Pharmaceuticals Limited on 16 July 2018 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 19 October 2018, 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.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for fosnetupitant / palonosetron (Akynzeo), powder for concentrate for solution for infusion, concentrate for solution for infusion, 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 Helsinn Birex Pharmaceuticals Limited, Damastown, Mulhuddart, Dublin 15 - Dublin, Ireland.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/493585/2018

London, 19 October 2018

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

EMA-001198-PIP03-17-M01

Scope of the application

Active substance(s):

Fosnetupitant / palonosetron

Invented name:

Akynzeo

Condition(s):

Prevention of chemotherapy-induced nausea and vomiting

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name / corporate name of the PIP applicant:

Helsinn Birex Pharmaceuticals 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, Helsinn Birex Pharmaceuticals Limited submitted to the European Medicines Agency on 16 July 2018 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/0140/2018 issued on 7 May 2018.

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

The procedure started on 21 August 2018.

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 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:

Prevention of chemotherapy-induced nausea and vomiting

The waiver applies to:

- newborn infants (from birth to less than 28 days);
- powder for concentrate for solution for infusion, concentrate for solution for infusion, intravenous 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 specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Prevention of chemotherapy-induced nausea and vomiting

2.1.1. Indication(s) targeted by the PIP

Prevention of acute and delayed nausea and vomiting associated with highly emetogenic and moderately emetogenic cancer chemotherapy.

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

From 1 month to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

- Powder for concentrate for solution for infusion
- Concentrate for solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Development of an age-appropriate dosage form for intravenous use
Non-clinical studies	2	Study 2 Dose range-finding study in juvenile rats Study 3 Definitive intravenous toxicity study with fosnetupitant in juvenile rats

Area	Number of measures	Description
Clinical studies	3	Study 4 (NEPA-15-31) Randomized, double-blind, dose-finding study involving two treatment groups receiving a single oral dose of netupitant administered concomitantly with a single oral dose palonosetron in paediatric cancer patients. Study 5 (NEPA-ORL-PED) Randomized, active-controlled, non-inferiority study in paediatric cancer patients to evaluate the efficacy and safety of netupitant/palonosetron fixed combination in comparison with aprepitant plus ondansetron regimen. Study 6 (NEPA-IV-PED) Open-label, non-comparative study in paediatric cancer patients to evaluate the safety and pharmacokinetics of IV fosnetupitant/palonosetron combination.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	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 August 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. Prevention of chemotherapy-induced nausea and vomiting

Authorised indication(s):

- Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy in adults.
- Prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults.

Authorised pharmaceutical form(s):

Hard capsules

Authorised route(s) of administration:

Oral use