EMA/364361/2020

# European Medicines Agency decision

P/0272/2020

of 13 July 2020

on the acceptance of a modification of an agreed paediatric investigation plan for fosnetupitant / palonosetron (Akynzeo), (EMEA-001198-PIP03-17-M04) 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/0140/2018 issued on 7 May 2018, the decision P/0344/2018 issued on 8 November 2018, the decision P/0267/2019 issued on 25 July 2019 and the decision P/0025/2020 issued on 7 January 2020,

Having regard to the application submitted by Helsinn Birex Pharmaceuticals Limited on 24 March 2020 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 26 June 2020, 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 fosnetupitant / palonosetron (Akynzeo), powder for concentrate for solution for infusion, concentrate for solution for infusion, intravenous 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 Helsinn Birex Pharmaceuticals Limited, Damastown, Mulhuddart, Dublin 15, Ireland.

EMA/PDCO/201933/2020
Amsterdam, 26 June 2020

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

EMEA-001198-PIP03-17-M04

## 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 24 March 2020 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 decision P/0344/2018 issued on 8 November 2018, the decision P/0267/2019 issued on 25 July 2019 and the decision P/0025/2020 issued on 7 January 2020.

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

The procedure started on 30 April 2020.

## Scope of the modification

Some measures 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 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**<br>Development of an age-appropriate dosage form for intravenous use |
| Non-clinical studies | 2 | **Study 2**<br>Dose range-finding study in juvenile rats<br>**Study 3**<br>Definitive intravenous toxicity study with fosnetupitant in juvenile rats |

| | | |
|---|---|---|
| Clinical studies | 3 | **Study 4** (NEPA-15-31)<br><br>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.<br><br>**Study 5** (NEPA-ORL-PED)<br><br>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.<br><br>**Study 6** (NEPA-IV-PED)<br><br>Open-label, non-comparative study in paediatric cancer patients to evaluate the safety and pharamcokinetics 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 December 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