EMA/400367/2023

European Medicines Agency decision

P/0399/2023

of 27 October 2023

on the acceptance of a modification of an agreed paediatric investigation plan for eptinezumab (Vyepti), (EMEA-002243-PIP01-17-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.

European Medicines Agency decision

P/0399/2023

of 27 October 2023

on the acceptance of a modification of an agreed paediatric investigation plan for eptinezumab (Vyepti), (EMEA-002243-PIP01-17-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0314/2019 issued on 11 September 2019, the decision P/0209/2020 issued on 16 June 2020, the decision P/0091/2022 issued on 11 March 2022, and the decision P/0341/2022 issued on 10 August 2022,

Having regard to the application submitted by H. Lundbeck A/S on 25 May 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 8 September 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 eptinezumab (Vyepti), 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 H. Lundbeck A/S, Ottiliavej 9, 2500 – Valby, Denmark.

EMA/PDCO/282416/2023
Amsterdam, 8 September 2023

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

EMEA-002243-PIP01-17-M04

Scope of the application

Active substance(s):

Eptinezumab

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of migraine headaches

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

H. Lundbeck A/S

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, H. Lundbeck A/S submitted to the European Medicines Agency on 25 May 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/0314/2019 issued on 11 September 2019, the decision P/0209/2020 issued on 16 June 2020, the decision P/0091/2022 issued on 11 March 2022, and the decision P/0341/2022 issued on 10 August 2022.

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

The procedure started on 10 July 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

Prevention of migraine headaches

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- solution for infusion, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition

Prevention of migraine headaches

2.1.1. Indication(s) targeted by the PIP

Prophylaxis of migraine

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

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for infusion

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	**Study 1** Study in juvenile rats to determine the potential toxicity of eptinezumab when administered once weekly (IV). (ALD403-086-TOX)
Clinical studies	**Study 2** Single arm, single-dose, pharmacokinetic study of eptinezumab in migraine patients 6 to less than 18 years of age for determination of effective dose

	Study 3 Randomised, double blind, placebo-controlled study to evaluate the efficacy and safety of eptinezumab for the prevention of chronic migraine (CM), in paediatric patients 12 to less than 18 years of age **Study 4** Randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of eptinezumab for the prevention of episodic migraine (EM) in paediatric patients from 6 to less than 18 years of age
Extrapolation, modelling and simulation studies	**Study 5** Population PK model to establish the initial paediatric dose to be used in the clinical efficacy and safety Studies 3 and 4. (ALD403-088-PK)
Other studies	Not applicable
Other measures	Not applicable

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 June 2027
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. Prevention of migraine headaches

Authorised indication(s):

- VYEPTI is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month

Authorised pharmaceutical form(s):

Concentrate for solution for infusion.

Authorised route(s) of administration:

Intravenous infusion.