EMA/284891/2024

European Medicines Agency decision

P/0224/2024

of 27 June 2024

on the acceptance of a modification of an agreed paediatric investigation plan for epcoritamab (Tepkinly), (EMEA-002907-PIP01-20-M03) 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/0344/2021 issued on 12 August 2021, the decision P/0257/2022 issued on 8 July 2022 and the decision P/0415/2022 issued on 29 September 2022,

Having regard to the application submitted by AbbVie Ltd on 22 February 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 31 May 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 epcoritamab (Tepkinly), concentrate for solution for injection, solution for injection, 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 AbbVie Ltd, AbbVie House, Vanwall Road, SL64UB – Maidenhead, United Kingdom.

EMA/PDCO/91759/2024
Amsterdam, 31 May 2024

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

EMEA-002907-PIP01-20-M03

Scope of the application

Active substance(s):

Epcoritamab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of mature B-cell malignancies

Pharmaceutical form(s):

Concentrate for solution for injection

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

AbbVie Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AbbVie Ltd submitted to the European Medicines Agency on 22 February 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/0344/2021 issued on 12 August 2021, the decision P/0257/2022 issued on 8 July 2022 and the decision P/0415/2022 issued on 29 September 2022.

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

The procedure started on 2 April 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.
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 mature B-cell malignancies

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- concentrate for solution for injection, solution for injection, subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

2. Paediatric investigation plan

2.1. Condition:

Treatment of mature B-cell malignancies

2.1.1. Indication(s) targeted by the PIP

Treatment of patients with mature B cell lymphoma after failure of first-line therapy

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

From 1 year to less than 18 years of age

2.1.3. Pharmaceutical form

Concentrate for solution for injection

Solution for injection

2.1.4. Measures

Area	**Description**
Quality-related studies	**Study 1** Development of an age appropriate dilution scheme
Non-clinical studies	Not applicable
Clinical studies	**Study 2 (M20-429)** Open-label, single arm trial, to evaluate pharmacokinetics, pharmacodynamics, safety, activity and immunogenicity of monotherapy epcoritamab in children (and adults) from 1 year to less than 18 years of age with mature B cell neoplasms

	Study 3 Open-label, randomised, active controlled trial to evaluate safety and efficacy, and immunogenicity of epcoritamab as add-on or alternative to standard of care compared to standard of care in children from 1 year to less than 18 years of age (and adults) with mature B cell lymphoma.
Extrapolation, modelling and simulation studies	**Study 4** Modelling and simulation study to determine the dose of epcoritamab in the proposed paediatric indication in children from 1 year to less than 18 years of age with mature B cell lymphoma.
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 November 2032
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 diffuse large B-cell lymphoma

Authorised indication:

- Tepkinly as monotherapy is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.
  - Invented name(s): Tepkinly
  - Authorised pharmaceutical form(s): Concentrate for solution for injection; solution for injection
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure