EMA/180112/2020

European Medicines Agency decision

P/0191/2020

of 15 May 2020

on the agreement of a paediatric investigation plan for cyclophosphamide (Zenew and associated names) (EMEA-002644-PIP01-19) 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 application submitted by Accord Healthcare S.L.U. on 12 August 2019 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 27 March 2020, in accordance with Article 17 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 agreement of a paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision agreeing a 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

A paediatric investigation plan for cyclophosphamide (Zenew and associated names), powder for oral solution, oral use, gastric use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

This decision is addressed to Accord Healthcare S.L.U., World Trade Center, Moll De Barcelona s/n, Edifici Est, 6a Planta, 08039 – Barcelona, Spain.

EMA/PDCO/25550/2020
Amsterdam, 27 March 2020

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan

EMEA-002644-PIP01-19

Scope of the application

Active substance(s):

Cyclophosphamide

Invented names:

Zenew and associated names

Condition(s):

Treatment of all malignant neoplasms

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for oral solution

Route(s) of administration:

Oral use

Gastric use

Name/corporate name of the PIP applicant:

Accord Healthcare S.L.U.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Accord Healthcare S.L.U. submitted for agreement to the European Medicines Agency on 12 August 2019 an application for a paediatric investigation plan for the above mentioned medicinal product, for which the applicant intends to submit an application for a paediatric use marketing authorisation.

The procedure started on 17 September 2019.

Supplementary information was provided by the applicant on 16 December 2019. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan 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 annex 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of all malignant neoplasms

2.1.1. Indication(s) targeted by the PIP

Cyclophosphamide is a cytotoxic drug for the treatment of malignant disease in children. As a single agent, it has successfully produced an objective remission in a wide range of malignant conditions. Cyclophosphamide is also frequently used in combination with other cytotoxic drugs, radiotherapy or surgery.

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)

Powder for oral solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a powder for oral solution.
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 2** (0068-20) Standard adult comparative bioequivalent study. **Study 3** (0069-20) Open label, single arm, multiple dose palatability study of cyclophosphamide oral solution of 150 mg/15 ml and 600 mg/20 ml strength in patients from birth to less than 18 years of age with a malignant disease requiring cyclophosphamide treatment.
Extrapolation, modelling and simulation studies	0	Not applicable.

Area	Number of measures	Description
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 2021
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of all malignant neoplasms

Authorised indication(s):

- Cyclophosphamide is a cytotoxic drug for the treatment of malignant disease in adults and children. As a single agent, it has successfully produced an objective remission in a wide range of malignant conditions. Cyclophosphamide is also frequently used in combination with other cytotoxic drugs, radiotherapy or surgery.

Authorised pharmaceutical form(s):

Coated tablet

Authorised route(s) of administration:

Oral use