EMA/147170/2023

European Medicines Agency decision

P/0131/2023

of 13 April 2023

on the acceptance of a modification of an agreed paediatric investigation plan for temozolomide (EMEA-002634-PIP01-19-M02) 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/0131/2023

of 13 April 2023

on the acceptance of a modification of an agreed paediatric investigation plan for temozolomide (EMEA-002634-PIP01-19-M02) 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/0147/2020 issued on 17 April 2020 and the decision P/0418/2021 issued on 29 October 2021.

Having regard to the application submitted by Accord Healthcare S.L.U. on 21 November 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 February 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.

(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, 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 temozolomide, powder for oral suspension, oral use, gastric 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 Accord Healthcare S.L.U., World Trade Center, Moll De Barcelona s/n, Edifici Est, 6a Planta, 08039 – Barcelona, Spain.

EMA/PDCO/925149/2022
Amsterdam, 24 February 2023

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

EMEA-002634-PIP01-19-M02

Scope of the application

Active substance(s):

Temozolomide

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of malignant glioma

Pharmaceutical form(s):

Powder for oral suspension

Route(s) of administration:

Oral use

Gastric use

Name/corporate name of the PIP applicant:

Accord Healthcare S.L.U.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Accord Healthcare S.L.U. submitted to the European Medicines Agency on 21 November 2022 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0147/2020 issued on 17 April 2020 and the decision P/0418/2021 issued on 29 October 2021.

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

The procedure started on 3 January 2023.

Scope of the modification

Some 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 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:

Treatment of malignant glioma

The request for the waiver applied to:

- the paediatric population from birth to less than 3 years of age;
- powder for oral suspension, oral use, gastric use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric investigation plan

2.1. Condition:

Treatment of malignant glioma

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients from the age of three years with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy, who have difficulty swallowing

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

From 3 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for oral suspension

2.1.4. Measures

Area	**Description**
Quality-related studies	**Study 1** (0627-19) Development of a powder for oral suspension
Non-clinical studies	Not applicable
Clinical studies	**Study 2** Standard adult bioequivalent study

	Study 3 (0756-19) Open label, single arm, multiple dose palatability study of temozolomide oral suspension in patients from 3 years to less than 18 years of age with malignant glioma requiring temozolomide treatment
Extrapolation, modelling and simulation studies	Not applicable
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:	No
Date of completion of the paediatric investigation plan:	By July 2024
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.