EMA/873552/2022

European Medicines Agency decision

P/0500/2022

of 1 December 2022

on the acceptance of a modification of an agreed paediatric investigation plan for gadoquatrane (BAY 1747846), (EMEA-002778-PIP01-20-M01) 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/0371/2020 issued on 23 October 2020.

Having regard to the application submitted by Bayer AG on 30 June 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 14 October 2022, 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 gadoquatrane (BAY 1747846), solution for injection, 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 Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 – Leverkusen, Germany.

EMA/PDCO/654116/2022 Corr[1]
Amsterdam, 14 October 2022

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

EMEA-002778-PIP01-20-M01

Scope of the application

Active substance(s):

Gadoquatrane (BAY 1747846)

Invented name and authorisation status:

See Annex II

Condition(s):

Diagnosis by evaluation of any known or suspected clinical condition with contrast enhanced magnetic resonance imaging

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Bayer AG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bayer AG submitted to the European Medicines Agency on 30 June 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/0371/2020 issued on 23 October 2020.

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

The procedure started on 16 August 2022.

[1] Correction as of 25 November 2022

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:

Diagnosis by evaluation of any known or suspected clinical condition with contrast enhanced magnetic resonance imaging

The waiver applies to:

- preterm newborn infants;
- solution for injection, intravenous 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:

Diagnosis by evaluation of any known or suspected clinical condition with contrast enhanced magnetic resonance imaging

2.1.1. Indication(s) targeted by the PIP

Contrast enhanced magnetic resonance tomography for the evaluation of suspected vasculature abnormalities, lesions or disease in any body region

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

From birth (infants born at term) to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	**Study 1 (TOXT103843-9)** Extended single dose toxicity study in juvenile rats after intravenous administration with a following recovery period up to 4 weeks.

	Study 2 (T104292-8) Repeated dose toxicity study in juvenile rats after intravenous administration with a following recovery period up to 8 weeks
Clinical studies	**Study 3 (21196)** Study to evaluate the pharmacokinetics (PK) of BAY 1747846 in paediatric patients to support the extrapolation of efficacy from adults.
Extrapolation, modelling and simulation studies	**Study 4 (CPMX50059)** Modelling and simulation study to evaluate the PK of BAY 1747846 in children from birth to less than 18 years of age and to extrapolate its efficacy for the diagnosis by evaluation with contrast enhanced magnetic resonance imaging from adults
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 June 2025
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.