

EMA/215110/2019

European Medicines Agency decision

P/0145/2019

of 17 April 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral for gadopiclenol (EMEA-001949-PIP02-18) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by GUERBET on 26 November 2018 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 1 March 2019, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 and on the granting of a deferral.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.

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 gadopichlenol, solution for injection, intravenous 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

A deferral for gadopichlenol, solution for injection, intravenous 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 granted.

Article 3

This decision is addressed to GUERBET, BP 57400 Roissy CDG Cedex, 95943 - ROISSY CDG, France.

EMA/PDCO/893404/2018

London, 1 March 2019

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

EMA-001949-PIP02-18

Scope of the application

Active substance(s):

Gadopiclenol

Condition(s):

Detection and visualization of disorders or lesions with suspected abnormal vascularity in various body regions for diagnostic purposes

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

GUERBET

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GUERBET submitted for agreement to the European Medicines Agency on 26 November 2018 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 3 January 2019.

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 18 of said Regulation;
- to grant a deferral in accordance with Article 21 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:

Detection and visualization of disorders or lesions with suspected abnormal vascularity in various body regions for diagnostic purposes

2.1.1. Indication(s) targeted by the PIP

Body MRI to detect and visualise lesions and abnormalities within the head and neck, thorax, abdomen, pelvis, and musculoskeletal system.

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)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1: Development of an additional volume for the solution for injection to avoid risk of overdose
Non-clinical studies	2	Study 2: Dose-range finding toxicity study in rats to determine the toxicity of gadopiclesol in the neonatal and juvenile (pre-post weaning) rats in order to determine appropriate dose levels for the definitive juvenile rat study. Study 3: Definitive juvenile toxicity study to determine the toxicity of gadopiclesol in the neonatal and juvenile (pre-post weaning) rats.
Clinical studies	2	Study 4: Non-comparative pharmacokinetics, efficacy and safety study in children from 2 to less than 18 years of age presenting central nervous system (CNS) lesions (intracranial, spine and associated tissues), who are scheduled to undergo routine contrast-enhanced MRI of CNS or body.

		Study 5: Non-comparative pharmacokinetic, efficacy and safety study in children from birth to less than 2 years of age scheduled to undergo routine contrast-enhanced MRI of CNS or body.
Extrapolation, modelling and simulation studies	0	Not applicable.
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 March 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes