EMA/662817/2022

# European Medicines Agency decision

P/0267/2022

of 4 August 2022

on the acceptance of a modification of an agreed paediatric investigation plan for gadopiclenol (EMEA-001949-PIP02-18-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.**

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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/0145/2019 issued on 17 April 2019 and the decision P/0151/2021 issued on 16 April 2021,

Having regard to the application submitted by Guerbet on 6 July 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 July 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 gadopiclenol, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0076/2017 issued on 17 March 2017, including subsequent modifications thereof.

***Article 3***

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

EMA/PDCO/637396/2022
Amsterdam, 22 July 2022

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

EMEA-001949-PIP02-18-M02

## Scope of the application

**Active substance(s):**

Gadopiclenol

**Condition(s):**

Detection and visualisation 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 22 of Regulation (EC) No 1901/2006 as amended, Guerbet submitted to the European Medicines Agency on 6 July 2022 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0145/2019 issued on 17 April 2019 and the decision P/0151/2021 issued on 16 April 2021.

The procedure started on 11 July 2022.

## Scope of the modification

An administrative modification to link two distinct PIPs for regulatory purposes.

## 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 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 visualisation 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**<br>Development of an additional volume for the solution for injection to avoid risk of overdose<br>*(This study is the same as Study 1 in EMEA-001949-PIP01-16 and subsequent modifications thereof.)* |
| Non-clinical studies | 2 | **Study 2**<br>Dose-range finding toxicity study in rats to determine the toxicity of gadopiclenol in the neonatal and juvenile (pre-post weaning) rats in order to determine appropriate dose levels for the definitive juvenile rat study<br>*(This study is the same as Study 2 in EMEA-001949-PIP01-16 and subsequent modifications thereof.)*<br>**Study 3**<br>Definitive juvenile toxicity study to determine the toxicity of gadopiclenol in the neonatal and juvenile (pre-post weaning) rats<br>*(This study is the same as Study 3 in EMEA-001949-PIP01-16 and subsequent modifications thereof.)* |

| | | |
|---|---|---|
| Clinical studies | 2 | **Study 4 (GDX-44-007)**<br><br>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<br><br>*(This study is the same as Study 4 in EMEA-001949-PIP01-16 and subsequent modifications thereof.)*<br><br>**Study 5**<br><br>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<br><br>*(This study is the same as Study 5 in EMEA-001949-PIP01-16 and subsequent modifications thereof.)* |
| 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 2024 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |