EMA/144653/2023

# European Medicines Agency decision

P/0117/2023

of 14 April 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral for pudexacianinium chloride (EMEA-003099-PIP01-21) 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 application submitted by Astellas Pharma Europe BV on 9 September 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 February 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

***Article 1***

A paediatric investigation plan for pudexacianinium chloride, powder for solution for injection, intravascular 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 pudexacianinium chloride, powder for solution for injection, intravascular 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 Astellas Pharma Europe BV, Sylviusweg 62, 2333 BE - Leiden, The Netherlands.

EMA/PDCO/940037/2022
Amsterdam, 24 February 2023

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

EMEA-003099-PIP01-21

## Scope of the application

**Active substance(s):**

Pudexacianinium chloride

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Visualisation of ureter

**Pharmaceutical form(s):**

Powder for solution for injection

**Route(s) of administration:**

Intravascular use

**Name/corporate name of the PIP applicant:**

Astellas Pharma Europe BV

## Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Astellas Pharma Europe BV submitted for agreement to the European Medicines Agency on 9 September 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 19 October 2021.

Supplementary information was provided by the applicant on 16 November 2022. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

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

   The Paediatric Committee member of Norway 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 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

Not applicable

# 2. Paediatric investigation plan

## *2.1. Condition:*

Visualisation of ureter

### 2.1.1. Indication(s) targeted by the PIP

Intraoperative visualisation of the ureter(s) in patients undergoing minimally invasive and open abdominopelvic surgeries

### 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 solution for injection

### 2.1.4. Measures

| Area | Description |
|---|---|
| Quality-related studies | Not applicable |
| Non-clinical studies | Not applicable |
| Clinical studies | **Study 1 (5354-CL-0301)**<br>Open-label, randomised study for intraoperative ureter visualisation when using pudexacianinium chloride with near-infrared fluorescence (NIR-F) imaging as compared to white light (WL) in children from 12 years to less than 18 years of age (and adults) undergoing minimally invasive and open abdominopelvic surgeries.<br>**Study 2 (5354-CL-0202)**<br>Open-label, uncontrolled study to evaluate pharmacokinetics, pharmacodynamics, safety and activity of pudexacianinium chloride when using near-infrared fluorescence (NIR-F) imaging for ureter visualisation as compared to white light in children from birth to less than 12 years of age undergoing minimally invasive and open abdominopelvic surgeries where ureter visualisation is indicated. |
| Modelling and simulation studies | **Study 3**<br>Modelling and simulation study to confirm dosing of pudexacianinium in adolescents and proposing doses in children from 2 years to less than 12 years of age. |

| | |
|---|---|
| | **Study 4**<br><br>Modelling and simulation study to support dosing of pudexacianinium chloride in children from 2 years to less than 12 years of age in the PIP study 2 (5354-CL-0202).<br><br>**Study 5**<br><br>Modelling and simulation study to support dosing of pudexacianinium chloride in children from birth to less than 2 years of age in the PIP study 2 (5354-CL-0202).<br><br>**Study 6**<br><br>Modelling and simulation study to support dosing of pudexacianinium chloride in children from birth to less than 12 years of age. |
| Other studies | Not applicable |
| Extrapolation plan | Studies 1, 2, 3, 4, 5 and 6 are part of an extrapolation plan covering the paediatric population from birth to less than 18 years of age, as agreed by the PDCO. |

# 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 2027 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

***Information provided by the applicant:***

**The product is not authorised anywhere in the European Community.**