MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-100872-PIP01-23

Scope of the Application

Active Substance(s)

pudexacianinium chloride

Condition(s)

Visualisation of ureter

Pharmaceutical Form(s)

Powder for solution for injection

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Astellas Pharma Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Astellas Pharma Ltd submitted to the licensing authority on 04/05/2023 10:31 BST an application for a Paediatric Investigation Plan

The procedure started on 26/09/2023 09:17 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100872-PIP01-23

Of 27/11/2023 18:32 GMT

On the adopted decision for pudexacianinium chloride (MHRA-100872-PIP01-23) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for pudexacianinium chloride, Powder for solution for injection , INTRAVENOUS USE .

This decision is addressed to Astellas Pharma Ltd, 300 Dashwood Lang Road, Bourne Business Park, Addlestone, Surrey, UNITED KINGDOM, KT15 2NX

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Visualisation of ureter

2.2 Indication(s) targeted by the PIP:

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

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder for solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 (5354-CL-0301) Open-label randomised, study for intraoperative ureter visualisation when using pudexacianinium with near-infrared fluorescence (NIR-F) imaging as compared to white light (WL) in children from 12 years less than 18 years of age (and adults) undergoing minimally invasive or open abdominopelvic surgeries. Study 2 (5354-CL-0202) Open-label, uncontrolled study to evaluate pharmacokinetics, pharmacodynamics, efficacy and safety of pudexacianinium 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 or open abdominopelvic surgeries where visualisation of the ureter is indicated.
Extrapolation, Modeling & Simulation Studies	5	Study 3 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 Modelling and simulation study to support dosing of pudexacianinium in children from 2 years to less than 12 years of age in

		PIP Study 2 (5354-CL-0202). Study 5 Modelling and simulation study to support dosing of pudexacianinium in children from birth to less than 2 years of age in PIP Study 2 (5354-CL-0202). Study 6 Modelling and simulation study to support dosing of pudexacianinium in children from birth to less than 12 years of age. Extrapolation Plan Studies 1, 2 ,3, 4, 5 and 6 are part of an extrapolation plan of efficacy data from adults to the paediatric population from birth to less than 18 years of age for the visualisation of ureters.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/06/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes