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 and grant a waiver

MHRA-101048-PIP01-23

Scope of the Application

Active Substance(s)

doruxapapogenum ralaplasmidum

Condition(s)

Treatment of recurrent respiratory papillomatosis

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Inovio Pharmaceuticals Inc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Inovio Pharmaceuticals Inc submitted to the licensing authority on 07/09/2023 15:22 BST an application for a Paediatric Investigation Plan

The procedure started on 04/12/2023 08:55 GMT

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 and grant a waiver

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-101048-PIP01-23

Of 15/11/2024 08:25 GMT

On the adopted decision for doruxapapogenum ralaplasmidum (MHRA-101048-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 doruxapapogenum ralaplasmidum, Solution for injection , INTRAMUSCULAR USE .

This decision is addressed to Inovio Pharmaceuticals Inc, 660 W. Germantown Pike, Suite 110 , Plymouth Meeting, UNITED STATES OF AMERICA, PA 19462

ANNEX I

1. Waiver

1.1 Condition:

Treatment of recurrent respiratory papillomatosis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age Pharmaceutical form(s): Solution for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of recurrent respiratory papillomatosis

2.2 Indication(s) targeted by the PIP:

Treatment of recurrent respiratory papillomatosis caused by HPV6 and/or HPV11

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

The paediatric population from 1 year to less than 18 years of age

2.4 Pharmaceutical Form(s):

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 (RRP-P01) 3-part randomised controlled, double-blind study to evaluate efficacy, safety and immunogenicity of doruxapapogenum ralaplasmidum in paediatric subjects from 1 year to less than 18 years of age for the treatment of HPV6- and/or HPV11-associated recurrent respiratory papillomatosis.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	31/12/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes