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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100334-PIP01-21-M01

Scope of the Application

Active Substance(s)

INDACATEROL ACETATE; GLYCOPYRRONIUM BROMIDE; MOMETASONE FUROATE

Condition(s)

Treatment of asthma

Pharmaceutical Form(s)

Inhalation powder, hard capsule

Route(s) of Administration

Inhalation use

Name / Corporate name of the PIP applicant

Novartis Pharmaceuticals UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Novartis Pharmaceuticals UK Limited submitted to the licensing authority on 22/11/2021 10:54 GMT an application for a Modification

The procedure started on 10/08/2022 17:26 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 accept change(s) to the agreed paediatric investigation plan and to the 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-100334-PIP01-21-M01

Of 31/08/2022 15:33 BST

On the adopted decision for INDACATEROL ACETATE; GLYCOPYRRONIUM BROMIDE; MOMETASONE FUROATE (MHRA-100334-PIP01-21-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for INDACATEROL ACETATE; GLYCOPYRRONIUM BROMIDE; MOMETASONE FUROATE, Inhalation powder, hard capsule , Inhalation use .

This decision is addressed to Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, United Kingdom, W12 7FQ

ANNEX I

1. Waiver

1.1 Condition:

Treatment of asthma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Inhalation powder, hard capsule Route(s) of administration: Inhalation use Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of asthma

2.2 Indication(s) targeted by the PIP:

Treatment of asthma

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

The paediatric population from 6 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Inhalation powder, hard capsule

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	3	Study 1 Double-blind, randomised, parallel-group, active-controlled study to evaluate the efficacy and safety of QVM149 in children from 12 years to less than 18 years of age with asthma. Study 2 Double-blind, randomised, multiple dose, cross over, three-treatment, three-period, six sequence, placebo-controlled trial to evaluate efficacy, pharmacokinetics (PK), pharmacodynamics (PD), and safety and tolerability of glycopyrronium (bromide) in children from 6 years to less than 12 years of age with asthma. Study 3 Double-blind, randomised, parallel-group, active-controlled study to evaluate the efficacy and safety of QVM149 in children from 6 years to less than 12 years of age with asthma.
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:	Yes
Date of completion of the paediatric investigation plan:	31/10/2028

Deferral of one or more studies contained in the paediatric investigation plan:	Yes