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 waiver

MHRA-100573-PIP01-22

Scope of the Application

Active Substance(s)

Vorasidenib (as hemicitrate, hemihydrate salt

Condition(s)

Treatment of glioma

Pharmaceutical Form(s)

Film-coated tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Les Laboratoires Servier

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Les Laboratoires Servier submitted to the licensing authority on 27/12/2022 22:52 GMT an application for a Paediatric Investigation Plan

The procedure started on 23/05/2023 15:29 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 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-100573-PIP01-22

Of 17/07/2023 10:20 BST

On the adopted decision for Vorasidenib (MHRA-100573-PIP01-22) 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 Vorasidenib, Film-coated tablet , ORAL USE .

This decision is addressed to Les Laboratoires Servier, 50 rue Carnot, Suresnes cedex, FRANCE, 92284

ANNEX I

1. Waiver

1.1 Condition:

Treatment of glioma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age Pharmaceutical form(s): Film-coated tablet Route(s) of administration: ORAL 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 glioma

2.2 Indication(s) targeted by the PIP:

Treatment of residual or recurrent Grade 2 glioma in patients with IDH1 or IDH2 mutation who have undergone surgery as their only treatment

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

The paediatric population from 12 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet

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 (AG881-C-004) Double-blind, randomised, placebo controlled trial to evaluate pharmacokinetics, safety and efficacy of Vorasidenib in children from 12 years to less than 18 years of age (and adults) with residual or recurrent grade 2 oligodendroglioma and astrocytoma with an IDH1 or IDH2 mutation and to provide exposure- response data to support the extrapolation of efficacity from adults.
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and simulation study to evaluate the use of the product in children from 12 years to less than 18 years of age with residual or recurrent Grade 2 oligodendroglioma and astrocytoma with an IDH1 or IDH2 mutation.
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:	30/06/2025
Deferral of one or more studies contained in the paediatric investigation plan:	No