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 grant a product specific waiver

MHRA-101409-PIP01-24-M01

Scope of the Application

Active Substance(s)

IVOSIDENIB

Condition(s)

Treatment of Acute Myeloid Leukaemia.

Pharmaceutical Form(s)

Film-coated tablets

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 20/03/2024 09:40 GMT an application for a Modification

The procedure started on 24/06/2024 20:50 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 grant a product specific 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-101409-PIP01-24-M01

Of 02/07/2024 16:36 BST

On the adopted decision for IVOSIDENIB (MHRA-101409-PIP01-24-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 and to grant a product specific waiver.

This decision applies to a Modification for IVOSIDENIB, Film-coated tablet , ORAL USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Acute Myeloid Leukaemia. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age. Pharmaceutical form(s): Film-coated tablet Route(s) of administration: ORAL USE Reason for granting waiver: on grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s). Paediatric Subset(s): The paediatric population from 2 years of age to less than 18 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):

Studies 1, 2, 3 and 4 were deleted during procedure MHRA-101409-PIP01-24-M01 and replaced by a full product specific waiver.

2.2 Indication(s) targeted by the PIP:

Not applicable.

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

Not applicable.

2.4 Pharmaceutical Form(s):

Not applicable.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	0	Not applicable.
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:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	