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

MHRA-100579-PIP01-22-M01

Scope of the Application

Active Substance(s)

Maribavir

Condition(s)

Treatment of cytomegalovius (CMV) infection

Pharmaceutical Form(s)

Film-coated tablet; Powder for oral suspension; Tablet for oral suspension

Route(s) of Administration

Oral Use

Name / Corporate name of the PIP applicant

Takeda Pharmaceuticals International AG Ireland Branch

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Takeda Pharmaceuticals International AG Ireland Branch submitted to the licensing authority on 21/06/2022 16:37 BST an application for a

The procedure started on 24/10/2022 17:45 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-100579-PIP01-22-M01

Of 07/11/2022 10:21 GMT

On the adopted decision for Maribavir (MHRA-100579-PIP01-22-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 for Maribavir, Film-coated tablet; Powder for oral suspension; Tablet for oral suspension , ORAL USE .

This decision is addressed to Takeda Pharmaceuticals International AG Ireland Branch, 50-58 Baggot Street Lower Block 3 Miesian Plaza, Dublin, IRELAND, D02 Y754

ANNEX I

1. Waiver

1.1 Condition:

Not Applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of cytomegalovius (CMV) infection

2.2 Indication(s) targeted by the PIP:

Treatment of CMV infection in paediatric patients who have undergone a haematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT).

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):

Film-coated tablet; Powder for oral suspension; Tablet for oral suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of a powder or tablet for oral suspension
Non-Clinical Studies	1	Study 2 (R11007M-SHP620) Definitive juvenile toxicity study in rats to evaluate potential gastrointestinal toxicity
Clinical Studies	3	Study 3 (SHP620-302) Double-blind, randomised, double-dummy, active-controlled trial to evaluate pharmacokinetics, safety, efficacy and acceptability of maribavir compared to valganciclovir for the treatment of asymptomatic CMV infection in adolescent and adult haematopoietic stem cell transplant (HSCT) recipients Study 4 deleted in EMEA-00353-PIP02-16-M01 Study 5 (TAK-620-1019). Open-label, randomised, single dose, three-treatment, three-period crossover study to assess the relative bioavailability, palatability, and safety/tolerability of the two candidate paediatric powder for oral suspension formulations of maribavir versus the adult tablet of maribavir in healthy adult volunteers Study 6 (TAK-620-2004) Open-label, single-arm, repeated dose trial to evaluate pharmacokinetics, safety, tolerability, antiviral activity and acceptability/palatability of maribavir for the treatment of CMV infection in children and adolescents from birth

		to less than 18 years of age who have received a HSCT
Extrapolation, Modeling & Simulation Studies	2	Study 7 Modelling and Simulation study to support paediatric dose finding and the extrapolation of use of maribavir for the treatment of CMV infection in children from birth to less than 18 years of age Study 8 Extrapolation study to support the use of maribavir for the treatment of CMV infections in children and adolescents from birth to less than 18 years of age who have received a SOT.
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:	28/02/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes