

EMA/825074/2022

European Medicines Agency decision P/0422/2022

of 28 October 2022

on the acceptance of a modification of an agreed paediatric investigation plan for maribavir (EMA-000353-PIP02-16-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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on the acceptance of a modification of an agreed paediatric investigation plan for maribavir (EMA-000353-PIP02-16-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/0315/2017 issued on 31 October 2017 and the decision P/0335/2020 issued on 31 August 2020,

Having regard to the application submitted by Takeda Pharmaceuticals International AG Ireland Branch on 27 May 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 September 2022, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

¹ OJ L 378, 27.12.2006, p.1, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for maribavir, tablet, tablet for oral suspension, powder for oral suspension, oral use, gastroenteral use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Takeda Pharmaceuticals International AG Ireland Branch, 50-58 Baggot Street Lower Block 3 Miesian Plaza, D02 Y754 - Dublin 2, Ireland.

EMA/PDCO/577335/2022
Amsterdam, 9 September 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000353-PIP02-16-M02

Scope of the application

Active substance(s):

Maribavir

Condition(s):

Treatment of cytomegalovirus infection

Pharmaceutical form(s):

Tablet

Tablet for oral suspension

Powder for oral suspension

Route(s) of administration:

Oral use

Gastroenteral use

Name/corporate name of the PIP applicant:

Takeda Pharmaceuticals International AG Ireland Branch

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Takeda Pharmaceuticals International AG Ireland Branch submitted to the European Medicines Agency on 27 May 2022 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0315/2017 issued on 31 October 2017 and the decision P/0335/2020 issued on 31 August 2020.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 11 July 2022.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report
 - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable.

2. Paediatric investigation plan

2.1. Condition

Treatment of cytomegalovirus (CMV) infection

2.1.1. 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).

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

Tablet for oral suspension

Powder for oral suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Development of a powder or tablet for oral suspension.
Non-clinical studies	1	Study 2 Definitive juvenile toxicity study in rats to evaluate potential gastrointestinal toxicity (R11007M-SHP620)
Clinical studies	3	Study 3 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 (SHP620-302). <i>Study 4:</i> <i>deleted in EMEA-00353-PIP02-16-M01</i> <i>Study 5:</i>

Area	Number of measures	Description
		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 (TAK-620-1019). Study 6: 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 (TAK-620-2004).
Extrapolation, modelling and 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 solid organ transplant (SOT).
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By February 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes