

EMADOC-1700519818-1811036

European Medicines Agency decision

EMA/PE/0000182607

of 3 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for maribavir (Livtency)
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 (Livtency) 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, the decision P/0335/2020 issued on 31 August 2020, the decision P/0422/2022 issued on 28 October 2022 and the decision P/0183/2023 issued on 19 May 2023,

Having regard to the application submitted by Takeda Pharmaceuticals International AG on 9 August 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 November 2024, 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.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

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 (Livtency), 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, Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2 - D02 HW68, Ireland.

EMADOC-1700519818-1677971
Amsterdam, 15 November 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA/PE/0000182607

Scope of the application

Active substance(s):

Maribavir

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of cytomegalovirus infection

Pharmaceutical form(s):

Film-coated tablet

Powder for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Takeda Pharmaceuticals International AG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Takeda Pharmaceuticals International AG submitted to the European Medicines Agency on 9 August 2024 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, the decision P/0335/2020 issued on 31 August 2020, the decision P/0422/2022 issued on 28 October 2022 and the decision P/0183/2023 issued on 19 May 2023.

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

The procedure started on 16 September 2024.

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 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 annexes 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	Description
Quality-related studies	Study 1 Development of a powder or tablet for oral suspension.
Non-clinical studies	Study 2 Definitive juvenile toxicity study in rats to evaluate potential gastrointestinal toxicity (R11007M-SHP620)
Clinical studies	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>

	Study 5: 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	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	Not applicable.
Other measures	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 May 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of cytomegalovirus infection

Authorised indication(s):

- Treatment of cytomegalovirus (CMV) infection and/or disease that are refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet in adult patients who have undergone a haematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT).
 - Invented name(s): Livtency
 - Authorised pharmaceutical form(s): Film-coated tablet
 - Authorised route(s) of administration: Oral use
 - Authorised via centralised procedure