EMA/852155/2022

European Medicines Agency decision

P/0496/2022

of 2 December 2022

on the acceptance of a modification of an agreed paediatric investigation plan for rilpivirine / dolutegravir (Juluca), (EMEA-001750-PIP01-15-M06) 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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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 726/2004[1],

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 Agency[2],

Having regard to the European Medicines Agency's decision P/0030/2016 issued on 29 January 2016, the decision P/0028/2017 issued on 10 February 2017, the decision P/0054/2019 issued on 11 February 2019, the decision P/0359/2020 issued on 9 September 2020, the decision P/0209/2021 issued on 10 May 2021 and the decision P/0524/2021 issued on 3 December 2021,

Having regard to the application submitted by ViiV Healthcare UK Limited on 4 July 2022 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 14 October 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 rilpivirine / dolutegravir (Juluca), film-coated tablet, oral 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 ViiV Healthcare UK Limited, 980 Great West Road, TW8 9GS - Brentford, Middlesex, United Kingdom.

EMA/PDCO/640479/2022
Amsterdam, 14 October 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001750-PIP01-15-M06

Scope of the application

Active substance(s):

Rilpivirine / dolutegravir

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

ViiV Healthcare UK Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ViiV Healthcare UK Limited submitted to the European Medicines Agency on 4 July 2022 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0030/2016 issued on 29 January 2016, the decision P/0028/2017 issued on 10 February 2017, the decision P/0054/2019 issued on 11 February 2019, the decision P/0359/2020 issued on 9 September 2020, the decision P/0209/2021 issued on 10 May 2021 and the decision P/0524/2021 issued on 3 December 2021.

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

The procedure started on 16 August 2022.

Scope of the modification

Some 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.
2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver 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

1.1. Condition:

Treatment of human immunodeficiency virus (HIV-1) infection

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- film-coated tablet; oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of human immunodeficiency virus 1 (HIV-1) infection

2.1.1. Indication(s) targeted by the PIP

Treatment of human immunodeficiency virus 1 (HIV-1) infection

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

From 6 years of age and weighing at least 25 kg to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Study deleted in EMEA-001750-PIP01-15-M04.
Non-clinical studies	Not applicable
Clinical studies	**Study 2 (201676)** Single dose, crossover pivotal bioequivalence evaluation of up to 2 fixed dose combination tablets of dolutegravir/rilpivirine compared to the co-administered reference formulations TIVICAY (dolutegravir) 50mg and EDURANT (rilpivirine) 25mg in healthy male and female adult volunteers

	Study 3 Multicentre, single-arm study to evaluate the pharmacokinetics, safety, tolerability and antiviral efficacy of switching to dual therapy, dolutegravir (DTG) plus rilpivirine (RPV), in anti-retroviral therapy (ART)-experienced HIV-1-infected children, from 6 years to less than 12 years of age who are virologically suppressed on their current anti-retroviral (ARV) regimen
Extrapolation, modelling and simulation studies	**Study 4** DTG paediatric PopPK model for determination of paediatric dose **Study 5** RPV paediatric PopPK model for determination of paediatric dose
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long-term efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2024.
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 of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

- Juluca is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically-suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for at least six months with no history of virological failure and no known or suspected resistance to any non-nucleoside reverse transcriptase inhibitor or integrase inhibitor
  - Invented name(s): Juluca
  - Authorised pharmaceutical form(s): film-coated tablet
  - Authorised route(s) of administration: oral use
  - Authorised via centralised procedure