EMA/929803/2022

European Medicines Agency decision

P/0523/2022

of 30 December 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for HIV-1 maturation inhibitor (GSK3640254) / dolutegravir (EMEA-003152-PIP01-21) 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 application submitted by ViiV Healthcare UK Limited on 10 December 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 November 2022, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[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

A paediatric investigation plan for HIV-1 maturation inhibitor (GSK3640254) / dolutegravir, film-coated tablet, age-appropriate oral dosage form, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for HIV-1 maturation inhibitor (GSK3640254) / dolutegravir, film-coated tablet, age-appropriate oral dosage form, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for HIV-1 maturation inhibitor (GSK3640254) / dolutegravir, film-coated tablet, age-appropriate oral dosage form, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to ViiV Healthcare UK Limited, 980 Great West Road, TW8 9GS - Brentford, United Kingdom.

EMA/PDCO/697254/2022
Amsterdam, 11 November 2022

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-003152-PIP01-21

Scope of the application

Active substance(s):

HIV-1 maturation inhibitor (GSK3640254) / 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

Age-appropriate oral dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

ViiV Healthcare UK Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, ViiV Healthcare UK Limited submitted for agreement to the European Medicines Agency on 10 December 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 31 January 2022.

Supplementary information was provided by the applicant on 22 July 2022. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

2. The measures and timelines of the agreed 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 2 years of age;
- film-coated tablet, age-appropriate oral dosage form, 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 (HIV-1) infection

2.1.1. Indication(s) targeted by the PIP

Treatment of HIV-1 infection in adolescents from 12 years to less than 18 years of age who are virologically-suppressed on a stable antiretroviral regimen and without current or past documented evidence of maturation inhibitor or integrase inhibitor resistance mutations.

Treatment of HIV-1 infection in children from 2 years to less than 12 years of age who are virologically-suppressed on a stable ARV regimen and with no prior history of switching for reasons other than toxicity or tolerability; and without current or past documented evidence of maturation inhibitor or integrase inhibitor resistance mutations.

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

From 2 years of age to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate oral dosage form

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of age-appropriate oral dosage forms for the paediatric population from 2 years to less than 6 years of age (weighing less than 20 kg) and from 6 years to less than 12 years of age (weighing at least 17 kg)
Non-clinical studies	Not applicable

Clinical studies	**Study 2 *(same as study 2 in EMEA-003153-PIP01-21)*** Open label, comparative study to evaluate the emergence of virologic failure, safety, tolerability and pharmacokinetics of GSK3640254/dolutegravir as compared to standard antiretroviral regimens in adolescents from 12 years to less than 18 years of age (and adults) with human immunodeficiency virus (HIV-1) infection. **Study 3 *(same as study 3 in EMEA-003153-PIP01-21)*** Open label, two-part study to evaluate the safety, tolerability, pharmacokinetics of GSK3640254/dolutegravir and maintenance and durability of virologic suppression in children from 2 years to less than 12 years of age with human immunodeficiency virus (HIV-1) infection
Modelling and simulation studies	**Study 4** Modelling and simulation study, to define the dose of GSK3640254/ dolutegravir to be used in children and adolescents from 2 years to less than 18 years of age with human immunodeficiency virus (HIV-1) infection and to confirm that the paediatric pharmacokinetic data collected in Study 2 and Study 3 are within the adult range values.
Other studies	Not applicable
Extrapolation plan	**Study 5** Extrapolation study to determine the use of GSK3640254/ dolutegravir in the paediatric population from 2 years to less than 18 years of age with human immunodeficiency virus (HIV-1) infection.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2029
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:

The product is not authorised anywhere in the European Community.