EMA/697703/2022

European Medicines Agency decision

P/0360/2022

of 22 August 2022

on the acceptance of a modification of an agreed paediatric investigation plan for cobicistat (Tybost), (EMEA-000969-PIP01-10-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/124/2011 issued on 7 June 2011, decision P/0239/2012 issued on 22 October 2012, decision P/0167/2013 issued on 30 July 2013, decision P/0212/2014 issued on 1 September 2014, decision P/0060/2017 issued on 17 March 2017, and decision P/0007/2021 issued on 15 January 2021,

Having regard to the application submitted by Gilead Sciences International Ltd. on 25 April 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and proposing a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 July 2022, in accordance with Article 22 of Regulation (EC) No 1901/2006 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 acceptance of changes to the agreed paediatric investigation plan and to the deferral and on the granting of a waiver.

(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.

(3) 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

Changes to the agreed paediatric investigation plan for cobicistat (Tybost), film-coated tablet, age appropriate tablet, age appropriate dispersible 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

A waiver for cobicistat (Tybost), film-coated tablet, age appropriate tablet, age appropriate dispersible tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Gilead Sciences International Ltd., Granta Park, Abington, CB21 6GT – Cambridge, United Kingdom.

EMA/PDCO/243510/2022 Corr
Amsterdam, 22 July 2022

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

EMEA-000969-PIP01-10-M06

Scope of the application

Active substance(s):

Cobicistat

Invented name:

Tybost

Condition(s):

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

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Age appropriate tablet

Age appropriate dispersible tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Gilead Sciences International Ltd.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Gilead Sciences International Ltd. submitted to the European Medicines Agency on 25 April 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/124/2011 issued on 7 June 2011, decision P/0239/2012 issued on 22 October 2012, decision P/0167/2013 issued on 30 July 2013, decision P/0212/2014 issued on 1 September 2014, decision P/0060/2017 issued on 17 March 2017, and decision P/0007/2021 issued on 15 January 2021.

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

The procedure started on 23 May 2022.

Scope of the modification

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

A waiver for a new paediatric subset has been added.

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,

   - to grant a waiver for one or more subsets of the paediatric population concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

Treatment of human immunodeficiency virus (HIV-1) infection

The waiver applies to:

- the paediatric population from birth to less than 3 months of age;
- film-coated tablet, age appropriate tablet, age appropriate dispersible tablet, oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition

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

2.1.1. Indication(s) targeted by the PIP

Treatment of human immunodeficiency virus type-1 (HIV-1) infection in paediatric patients - pharmacokinetic enhancer of atazanavir or darunavir for use in combination with antiretroviral agents

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

From 3 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age appropriate tablet

Age appropriate dispersible tablet

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of an age-appropriate tablet. **Study 2** Development of an age-appropriate dispersible tablet.
Non-clinical studies	Not applicable.
Clinical studies	**Study 3** (GS-US-216-0127) Open-label, randomised crossover trial in healthy adult subjects to determine the relative bioavailability of the adult cobicistat film-coated tablet to an age-appropriate tablet (Cohort 1) and to an age-appropriate dispersible tablet (Cohort 2).

	Study 4 (GS-US-216-0128) Open-label trial to evaluate pharmacokinetics, safety and efficacy of once-daily cobicistat-boosted atazanavir administered with a background regimen in HIV-1 infected, treatment-experienced children aged from 3 months to less than 18 years of age or once-daily cobicistat-boosted darunavir administered with a background regimen in HIV-1 infected, treatment-experienced children aged from 3 years to less than 18 years of age.
Extrapolation, modelling and simulation studies	Not applicable.
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:	Yes
Date of completion of the paediatric investigation plan:	By September 2025
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

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

Authorised indication(s):

- Tybost is indicated as a pharmacokinetic enhancer of atazanavir 300 mg once daily or darunavir 800 mg once daily as part of antiretroviral combination therapy in human immunodeficiency virus-1 (HIV-1) infected adults.

Authorised pharmaceutical form(s)

Film-coated tablet

Authorised route(s) of administration

Oral use