EMA/694481/2020

European Medicines Agency decision

P/0007/2021

of 15 January 2021

on the acceptance of a modification of an agreed paediatric investigation plan for cobicistat (Tybost), (EMEA-000969-PIP01-10-M05) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary 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, the decision P/0239/2012 issued on 22 October 2012, the decision P/0167/2013 issued on 30 July 2013, the decision P/0212/2014 issued on 1 September 2014 and the decision P/0060/2017 issued on 17 March 2017,

Having regard to the application submitted by Gilead Sciences International Ltd. on 11 September 2020 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 11 December 2020, 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.
[2] OJ L 136, 30.4.2004, p. 1.

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, 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 Gilead Sciences International Ltd., Granta Park, Abington, CB21 6GT – Cambridge, United Kingdom.

EMA/PDCO/495727/2020 Corr
Amsterdam, 11 December 2020

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

EMEA-000969-PIP01-10-M05

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 11 September 2020 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, the decision P/0239/2012 issued on 22 October 2012, the decision P/0167/2013 issued on 30 July 2013, the decision P/0212/2014 issued on 1 September 2014 and the decision P/0060/2017 issued on 17 March 2017.

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

The procedure started on 13 October 2020.

Scope of the modification

Some measures 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 Norwegian Paediatric Committee member 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 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 birth 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	**Number of studies**	**Description**
Quality-related studies	2	**Study 1** Development of an age-appropriate tablet. **Study 2** Development of an age-appropriate dispersible tablet.
Non-clinical studies	0	Not applicable.

Clinical studies	2	**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	0	Not applicable.
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:	Yes.
Date of completion of the paediatric investigation plan:	By August 2019
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)

1. Treatment of 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