EMA/526334/2023

European Medicines Agency decision

P/0462/2023

of 1 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for bemnifosbuvir (EMEA-002963-PIP01-21-M01) 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

European Medicines Agency decision

P/0462/2023

of 1 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for bemnifosbuvir (EMEA-002963-PIP01-21-M01) 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 726/2004[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/0463/2021 issued on 29 October 2021,

Having regard to the application submitted by Atea Pharmaceuticals, Inc on 30 June 2023 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 13 October 2023, 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 bemnifosbuvir, tablet, age-appropriate oral dosage form, 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 Atea Pharmaceuticals, Inc, 225, Franklin Street Suite, 2100, 02110 - Boston, United States.

EMA/PDCO/317021/2023
Amsterdam, 13 October 2023

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

EMEA-002963-PIP01-21-M01

Scope of the application

Active substance(s):

Bemnifosbuvir

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Tablet

Age-appropriate oral dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Atea Pharmaceuticals, Inc

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Atea Pharmaceuticals, Inc submitted to the European Medicines Agency on 30 June 2023 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0463/2021 issued on 29 October 2021.

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

The procedure started on 14 August 2023.

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 and to the deferral 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 coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Treatment of COVID-19 in paediatric patients from birth to less than 18 years of age at risk of progressing to severe disease.

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

Age-appropriate oral dosage form

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of an age-appropriate formulation of bemnifosbuvir for use in paediatric COVID-19 patients from birth to less than 12 years of age.
Non-clinical studies	Not applicable
Clinical studies	**Study 2** *Study deleted in EMEA-002963-PIP01-21-M01*. **Study 3** Single arm study to assess pharmacokinetics, antiviral activity, safety, and exploratory efficacy of bemnifosbuvir treatment of paediatric patients from birth to less than 12 years of age with mild to moderate COVID-19. **Study 7** *Study added in EMEA-002963-PIP01-21-M01.* Multicenter, randomized, double-blind, placebo-controlled, outpatient study in adolescents from 12 years to less than 18 years of age (and adults) to evaluate the efficacy, safety, and pharmacokinetics of bemnifosbuvir (BEM) in COVID-19 outpatients at risk of progression to severe disease receiving only supportive care.

Extrapolation, modelling and simulation studies	**Study 4** Population pharmacokinetic (PK) model describing jointly the PK of AT-511 (free base form of bemnifosbuvir) and AT-273 (the surrogate for the intracellular concentration of the active triphosphate metabolite AT-9010) in paediatric (and adult) patients from 12 years to less than 18 years of age with mild or moderate COVID-19. **Study 5** Bayesian feedback analysis of the pharmacokinetic (PK) data collected in paediatric patients (birth to less 12 years) with COVID-19 using the integrated population PK model (Study 4) to support extrapolation of efficacy data establishing that the PK of AT-511 and AT-273 is similar between paediatric and adult patients with COVID-19. **Study 6** Extrapolation study of efficacy and safety of bemnifosbuvir from adult subjects to paediatric patients from birth to less than 18 years of age with confirmed COVID-19. **Study 8** *Study added in EMEA-002963-PIP01-21-M01.* Physiologically based pharmacokinetic (PBPK) modelling study to support dose finding in the paediatric population.
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 July 2027
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.