EMADOC-1700519818-1907112
Corr[1]

European Medicines Agency decision

EMEA-003192-PIP03-23

of 12 February 2025

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

[1] 10 April 2025, Article 3 included

European Medicines Agency decision

EMEA-003192-PIP03-23

of 12 February 2025

on the agreement of a paediatric investigation plan and on the granting of a deferral for ensitrelvir 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[2],

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[3],

Having regard to the application submitted by Shionogi B.V. on 19 November 2023 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric and Committee of the European Medicines Agency, issued on 31 January 2025, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 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 on the agreement of a paediatric investigation plan and on the granting of a deferral.

(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.

[2] OJ L 378, 27.12.2006, p.1, as amended.
[3] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation for ensitrelvir, 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 ensitrelvir, 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

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0242/2024 issued on 19 July 2024, including subsequent modifications thereof.

Article 4

This decision is addressed to Shionogi B.V., Herengracht 464, 1017 CA - Amsterdam, Netherlands.

EMADOC-1700519818-1789525
Amsterdam, 31 January 2025

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

EMEA-003192-PIP03-23

Scope of the application

Active substance(s):

Ensitrelvir

Invented name and authorisation status:

See Annex II

Condition(s):

Post-exposure prophylaxis of coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Granules

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Shionogi B.V.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Shionogi B.V. submitted for agreement to the European Medicines Agency on 19 November 2023 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 3 January 2024.

Supplementary information was provided by the applicant on 27 November 2024. 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.
2. The measures and timelines of the agreed 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:

Post-exposure prophylaxis of coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Post-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in children from birth to less than 18 years of age who are at increased risk of progressing to severe disease and who do not require supplemental oxygen

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)

Age-appropriate oral solid dosage form

Tablets

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of an age-appropriate granule dosage form of ensitrelvir for use in patients from birth to less than 18 years of age **Study 2** Development of a lower strength tablet of ensitrelvir for use in patients from 6 years of age to less than 18 years of age
Non-clinical studies	**Study 3** (**S-217622-TF-200-L)** Toxicity and toxicokinetic study in rats from postnatal days 4 to 20, to support the development of ensitrelvir for use in children from birth to less than 2 years of age
Clinical studies	**Study 4** Open-label, single-arm study to evaluate the pharmacokinetics, safety, and tolerability of ensitrelvir in non-hospitalised high-risk paediatric patients from birth to

	less than 18 years of age with laboratory confirmed SARS-CoV-2 infection **Study 5 (SCORPIO-PEP)** Randomized, double-blind, parallel-group, placebo-controlled comparative study in adolescents from 12 years to less than 18 years of age (and adults) who are uninfected household contacts of symptomatic SARS-CoV-2-infected index patients **Study 6** Study to evaluate the efficacy, safety, pharmacokinetics and antiviral activity of ensitrelvir for post-exposure prophylaxis of COVID-19 in immunocompromised children from birth to less than 18 years of age
Modelling and simulation analyses	**Study 7** Modelling and simulation study to support the use of ensitrelvir in paediatric patients with COVID-19 from birth to less than 18 years of age
Other studies	Not applicable
Extrapolation plan	Studies SCORPIO-Standard Risk (adult and adolescent patients with COVID-19), SCORPIO-High Risk (adults with COVID-19), and Studies 4 5, 6, and 7 of this PIP are part of an extrapolation plan covering the paediatric population from birth to less than 18 years of age, as agreed by the PDCO

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 May 2032
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.