MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-100999-PIP02-23

Scope of the Application

Active Substance(s)

Ensitrelvir

Condition(s)

Treatment of coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

Tablet; Age-appropriate oral solid dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Shionogi B.V

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Shionogi B.V submitted to the licensing authority on 27/10/2023 10:35 BST an application for a Paediatric Investigation Plan

The procedure started on 25/01/2024 12:47 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100999-PIP02-23

Of 18/12/2024 07:06 GMT

On the adopted decision for Ensitrelvir (MHRA-100999-PIP02-23) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Ensitrelvir, Tablet; Age-appropriate oral solid dosage form , ORAL USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of coronavirus disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Treatment of SARS-CoV-2 infection in paediatric patients who are at increased risk of progression to severe disease and who do not require supplemental oxygen.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Age-appropriate oral solid dosage form Tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	2	Study 1 Development of an ensitrelvir age-appropriate granule dosage form for use in patients from birth to less than 18 years of age. Study 2 Development of an ensitrelvir lower strength tablet for use in patients from 6 years to less than 18 years of age.
Non-Clinical Studies	1	Study 3 (S-217622-TF-200-L) Toxicity and toxicokinetic study in SD rats from postnatal days 4 to 20, to support the development of ensitrelvir for use in humans from birth to less than 2 years of age.
Clinical Studies	1	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.
Extrapolation, Modeling & Simulation Studies	2	Study 5 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. Extrapolation Plan SCORPIO-Standard Risk (adult and adolescent patients with COVID-19), SCORPIO-High Risk (adults with COVID-19), and Studies 4 and 5 of this PIP are part of an extrapolation plan covering the paediatric population from birth to less than 18 years of age.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/12/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes