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-100971-PIP01-23

Scope of the Application

Active Substance(s)

Sipavibart (AZD3152)

Condition(s)

Prevention of Coronavirus Disease 2019 (COVID-19)

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAMUSCULAR USE, INTRAVENOUS USE

Name / Corporate name of the PIP applicant

AstraZeneca UK Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Ltd submitted to the licensing authority on 14/04/2023 17:30 BST an application for a Paediatric Investigation Plan

The procedure started on 10/07/2023 08:02 BST

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-100971-PIP01-23

Of 18/12/2023 13:45 GMT

On the adopted decision for Sipavibart (AZD3152) (MHRA-100971-PIP01-23) 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 Sipavibart (AZD3152), Solution for injection , INTRAMUSCULAR USE INTRAVENOUS USE .

This decision is addressed to AstraZeneca UK Ltd, Biomedical Campus, 1 Francis Crick Ave, Trumpington, Cambridge , UNITED KINGDOM, CB2 0AA

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Coronavirus Disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Pre-exposure prophylaxis of COVID-19 in children who are at risk for developing severe disease.

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

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 (POLARIS) Open label, uncontrolled, single dose study to evaluate safety, tolerability and pharmacokinetics of AZD3152 in paediatric subjects from 29 weeks gestational age (GA) to less than 18 years of age immunocompromised and/or at increased risk of developing severe COVID-19.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Population PK model (PopPK) for AZD3152 dose prediction and confirmation in paediatric patients from 29 weeks gestational age (GA) to less than 18 years of age immunocompromised and/or at increased risk of developing severe COVID-19. Extrapolation plan Studies 1 and 2 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