MHRA
10 South Colonnade
Canary Wharf
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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-100028-PIP01-21

Scope of the Application

Active Substance(s)

AZD 7442; tixagevimab (AZD8895); cilgavimab (AZD1061)

Condition(s)

Prevention of Coronavirus Disease 2019 (COVID-19), Treatment of Coronavirus Disease 2019 (COVID-19)

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Intramuscular use

Name / Corporate name of the PIP applicant

AstraZeneca UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 28/04/2021 17:34 BST an application for a Paediatric Investigation Plan

The procedure started on 28/04/2021 08:34 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:

The agreement of a paediatric investigation plan and on the granting of 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-100028-PIP01-21

Of 05/08/2021 08:08 BST

On the adopted decision for AZD 7442; tixagevimab (AZD8895); cilgavimab (AZD1061) (MHRA-100028-PIP01-21) 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 AZD 7442; tixagevimab (AZD8895); cilgavimab (AZD1061), Solution for injection , Intramuscular use .

This decision is addressed to AstraZeneca UK Limited, 600 Capability Green, Luton, United Kingdom, LU1 3LU

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Coronavirus Disease 2019 (COVID-19), Treatment of Coronavirus Disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Pre- and post-exposure prophylaxis of Coronavirus Disease 2019 (COVID-19) in children who are at risk of progressing to severe disease; Treatment of paediatric patients with Coronavirus Disease 2019 (COVID-19) who are at risk of progressing to 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 Open label, uncontrolled, single dose study to evaluate pharmacokinetics (PK), pharmacodynamics (PD) and safety of tixagevimab and cilgavimab for the treatment of paediatric patients with mild to moderate COVID-19 at high risk for developing severe disease and for pre and post-exposure prophylaxis in paediatric subjects from 29 weeks gestational age (GA) to less than 18 years of age at high risk of developing severe COVID-19.
Extrapolation, Modeling & Simulation Studies	3	Study 2 A two-compartment population PK model for dose prediction in children from 29 weeks gestational age to less than 18 years of age. Study 3 PK bridging and extrapolation of clinical efficacy and safety of tixagevimab and cilgavimab for pre- and post-exposure prophylaxis of COVID-19 in adults at risk of developing severe disease to efficacy and safety for pre- and postexposure prophylaxis of COVID-19 in paediatric populations from 29 weeks gestational age to less than 18 years of age at risk of developing severe disease. Study 4 PK bridging and extrapolation of clinical efficacy and safety

		of tixagevimab and cilgavimab for treatment of mild-moderate COVID-19 in adult patients at risk of developing severe disease to efficacy and safety for treatment of mild-moderate COVID-19 in paediatric patients from 29 weeks gestational age to less than 18 years of age at risk of developing severe disease.
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:	30/06/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes