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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-100724-PIP01-22

Scope of the Application

Active Substance(s)

tozorikamab

Condition(s)

Treatment of severe viral lower respiratory tract infection

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAVENOUS 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 04/01/2023 16:20 GMT an application for a Paediatric Investigation Plan

The procedure started on 05/06/2023 19:05 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100724-PIP01-22

Of 20/06/2024 21:57 BST

On the adopted decision for tozorikamab (MHRA-100724-PIP01-22) 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 tozorikamab, Solution for injection , INTRAVENOUS USE .

This decision is addressed to AstraZeneca UK Limited, 2 Pancras Square, 8th Floor, London, UNITED KINGDOM, N1C 4AG

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of severe viral lower respiratory tract disease

2.2 Indication(s) targeted by the PIP:

Treatment of severe viral lower respiratory tract disease

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):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate lower dose strength solution for injection, intravenous use, for the paediatric population from birth to less than 2 years of age.
Non-Clinical Studies	1	Study 2 (Enhanced pre- and postnatal development study) To assess potential maternal and developmental effects of tozorakimab, and to evaluate growth and development of infants for 6 months postnatally after administration of tozorakimab to birth mothers during gestation.
Clinical Studies	3	Study 3 Open-label, 2-part, single-dose, single-arm trial to evaluate the pharmacokinetics and safety of tozorakimab as add-on to standard of care in children from birth to less than 18 years of age, hospitalised with suspected viral lower respiratory tract disease requiring supplemental oxygen. Study 4 Double-blind, randomised, single dose, parallel arm, placebo-controlled trial to evaluate efficacy and safety of tozorakimab in children from birth to less than 2 years of age hospitalised with suspected or confirmed viral lower respiratory tract disease requiring supplemental oxygen. Study 5 Open-label study to evaluate the safety, pharmacokinetics (PK), pharmacodynamics (PD) and immunogenicity of tozorakimab in children from 2 years to less than 18 years of age hospitalised with

		suspected or confirmed viral lower respiratory tract disease (LRTD) requiring supplemental oxygen.
Extrapolation, Modeling & Simulation Studies	2	Study 6 (Population Pharmacokinetic model) To define doses and sample size for PIP Study 2 3, and to define doses for PIP Study 4 and 5. Study 7 (Population Pharmacokinetic/ Pharmacodynamic Model) PopPK/ PD model with efficacy and/ or PD data from Phase 3 in adults and available data from paediatric population (PIP studies 3, 4 and 5), to assist with the extrapolation of efficacy from adults and paediatric patients from birth to less than 2 years of age to the paediatric population from 2 years of age 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:	30/06/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes