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 and grant a waiver

MHRA-102543-PIP01-26

Scope of the Application

Active Substance(s)

tozorakimab

Condition(s)

Treatment of asthma

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Subcutaneous 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 19/06/2026 18:21 BST an application for a Paediatric Investigation Plan

The procedure started on 01/07/2026 08:09 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 and grant a waiver

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-102543-PIP01-26

Of 22/10/2026 09:25 BST

On the adopted decision for tozorakimab (MHRA-102543-PIP01-26) 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 tozorakimab, Solution for injection , Subcutaneous use .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of asthma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Subcutaneous use Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of asthma

2.2 Indication(s) targeted by the PIP:

Add-on maintenance therapy for uncontrolled asthma in patients 2 years and older despite the daily use of controller medications described in Step 4 or 5 of the GINA guidelines.

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

The paediatric population from 2 years 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	4	Study 1 Double-blind, randomised, placebo controlled, parallel study to evaluate the efficacy, safety, tolerability, pharmacokinetics and immunogenicity of tozorakimab in adolescents from 12 years to less than 18 years of age (and adults) with uncontrolled asthma on medium to high dose of inhaled corticosteroid (ICS) and long-acting beta-agonist (LABA) and $\geq$1 exacerbation in the last 12 months. Study 2 Open-label, single-arm, single-dose study to characterise the pharmacokinetic profile and evaluate the safety and tolerability of a single-dose of tozorakimab in children from 5 years to less than 12 years of age. Study 3 Randomised, double-blind, placebo controlled, parallel group study to evaluate the efficacy, safety, tolerability, PK and immunogenicity of tozorakimab in children from 5 years to less than 18 years of age with uncontrolled asthma on medium or high dose ICS and at least 1 additional controller medication. Study 4 Study to evaluate the efficacy and safety of tozorakimab in children from 2 years to less than

		5 years of age with uncontrolled asthma and/or recurrent wheezing.
Extrapolation, Modeling & Simulation Studies	1	Study 5 Population pharmacokinetic model to predict exposures of tozorakimab in the paediatric population aged from 2 years to less than 18 years of age and to assist dose selection for the paediatric population to be used in Studies 1, 2, 3 and 4.
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:	30/06/2041
Deferral of one or more studies contained in the paediatric investigation plan:	Yes