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-100146-PIP01-21

Scope of the Application

Active Substance(s)

Tezepelumab

Condition(s)

Treatment of eosinophilic esophagitis

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS 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 29/07/2021 14:56 BST an application for a Paediatric Investigation Plan

The procedure started on 12/12/2022 11:36 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 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100146-PIP01-21

Of 15/07/2024 13:20 BST

On the adopted decision for Tezepelumab (MHRA-100146-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 Tezepelumab, Solution for injection , Subcutaneous use .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of eosinophilic esophagitis 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 eosinophilic esophagitis

2.2 Indication(s) targeted by the PIP:

Treatment of eosinophilic esophagitis in children from 2 years of age and older.

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	2	Study 1 (D5244C00001) Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of tezepelumab in adolescents from 12 years to less than 18 years of age (and adults) of age with eosinophilic esophagitis (EoE). Study 2 (Paediatric efficacy and safety in EoE) Open-label, uncontrolled trial to evaluate safety and activity of tezepelumab in children from 2 years to less than 12 years of age with eosinophilic esophagitis (EoE).
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulation for dose selection. Study 4 Modelling and simulation for dose confirmation.
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:	Yes
Date of completion of the paediatric investigation plan:	31/05/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes