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 and grant a waiver

MHRA-100508-PIP01-22

Scope of the Application

Active Substance(s)

tezepelumab

Condition(s)

Treatment of chronic spontaneous urticaria

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Amgen Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Amgen Limited submitted to the licensing authority on 27/05/2022 09:20 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.

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Final Decision Letter

MHRA-100508-PIP01-22

Of 06/01/2023 07:31 GMT

On the adopted decision for tezepelumab (MHRA-100508-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 tezepelumab, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Amgen Limited, 216 Cambridge Science Park, Milton Road, Cambridge, UNITED KINGDOM, CB4 0WA

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic spontaneous urticaria 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 clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of chronic spontaneous urticaria

2.2 Indication(s) targeted by the PIP:

Treatment of children and adolescents with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1-antihistamine treatment

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 Randomised, double-blind, placebo-controlled, parallel-group, study to evaluate the efficacy and safety of the tezepelumab in adolescent patients from 12 years to less than 18 years of age (and in adults) with chronic spontaneous urticaria (CSU). Study 2 Open label, single-group, multi-dose study to assess the safety and pharmacokinetics and to explore efficacy of tezepelumab in children from 2 years to less than 12 years of age, with chronic spontaneous urticaria (CSU).
Extrapolation, Modeling & Simulation Studies	3	Study 3 Modelling and simulation study to select the appropriate dose(s) of Tezepelumab for the adolescent population in study 1. Study 4 Modelling and simulation study to confirm that the selected dose(s) based on the population PK model resulted in expected exposures which have been associated with efficacy (matching exposure to adults and adolescents at the efficacious dose). Study 5 Extrapolation of efficacy of tezepelumab from adult and/or adolescent population to infer treatment effect in the paediatric

		population from 2 years to less than 12 years of age with moderate-to-severe CSU.
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:	31/12/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes