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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100141-PIP01-21) and to the deferral

MHRA-100141-PIP01-21-M01

Scope of the Application

Active Substance(s)

BENRALIZUMAB

Condition(s)

Treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA)

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 16/05/2023 14:55 BST an application for a Modification

The procedure started on 04/10/2023 07:24 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 accept change(s) to the agreed paediatric investigation plan and to the 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-100141-PIP01-21-M01

Of 16/10/2023 10:03 BST

On the adopted decision for BENRALIZUMAB (MHRA-100141-PIP01-21-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for BENRALIZUMAB, Solution for injection , SUBCUTANEOUS USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 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 Granulomatosis with Polyangiitis (EGPA)

2.2 Indication(s) targeted by the PIP:

Treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA)

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

The paediatric population from 6 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	1	Study 1 Development of an age-appropriate presentation (solution for injection in a pre-filled syringe) suitable for children from 6 years of age.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 (CLIPS) Open label uncontrolled trial to evaluate safety, pharmacokinetics (PK), pharmacodynamics (PD), activity and immunogenicity of benralizumab in children from 6 years to less than 18 years of age with EGPA, plus paediatric patients with other eosinophilic diseases.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulation study to evaluate benralizumab use in children from 6 years to less than 18 years of age with EGPA, plus paediatric patients with other eosinophilic diseases. Study 4 Extrapolation study in children and adolescents with EGPA from 6 years to less than 18 years of age, based on population pharmacokinetics (PK) and population PK/ pharmacodynamics (PD) models and clinical data.
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:	30/06/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes