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-100141-PIP01-21

Scope of the Application

Active Substance(s)

BENRALIZUMAB

Condition(s)

Treatment of Eosinophilic Granulomatosis with Polyangitis (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 12/08/2021 11:15 BST an application for a Paediatric Investigation Plan

The procedure started on 20/06/2022 10:35 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-100141-PIP01-21

Of 07/07/2022 16:17 BST

On the adopted decision for BENRALIZUMAB (MHRA-100141-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 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 Polyangitis (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 Polyangitis (EGPA)

2.2 Indication(s) targeted by the PIP:

Treatment of Eosinophilic Granulomatosis with Polyangitis (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 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 year 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