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-100056-PIP01-21

Scope of the Application

Active Substance(s)

BENRALIZUMAB

Condition(s)

Eosinophilic gastritis (EG) and eosinophilic gastroenteritis (EGE)

Pharmaceutical Form(s)

Solution for injection; solution for injection/ infusion; Age-appropriate dosage form for parenteral use

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 06/05/2021 10:28 BST an application for a Paediatric Investigation Plan

The procedure started on 14/12/2021 17:13 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-100056-PIP01-21

Of 21/01/2022 09:06 GMT

On the adopted decision for BENRALIZUMAB (MHRA-100056-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; solution for injection/ infusion; Age-appropriate dosage form for parenteral use , 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 gastritis and eosinophilic gastroenteritis 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; Solution for injection / infusion; Age-appropriate dosage form for parenteral use 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 gastritis (EG) and eosinophilic gastroenteritis (EGE)

2.2 Indication(s) targeted by the PIP:

Treatment of eosinophilic gastritis (EG) and eosinophilic gastroenteritis (EGE)

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

The paediatric population 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection; Solution for injection/ infusion; Age-appropriate dosage form for parenteral use

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of appropriate dosage form and formulation to enable weight-based dosing in patients younger than 6 years of age weighing less than 15 kg.
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 2 (D3258C00001; HUDSON) Double-blind randomised, placebo-controlled study to compare the efficacy and safety of benralizumab in adolescents from 12 years to less than 18 years of age (and adults) with eosinophilic gastritis and/or eosinophilic gastroenteritis (EG/EGE) Study 3 (CLIPS) Open label non-comparative study to evaluate safety, pharmacokinetics (PK), pharmacodynamic (PD), and immunogenicity of benralizumab in children from 2 years to less than 12 years of age with eosinophilic gastritis and/or eosinophilic gastroenteritis (EG/EGE) or other eosinophilic diseases.
Extrapolation, Modeling & Simulation Studies	2	Study 4 Modelling and simulation study (population pharmacokinetics/ pharmacodynamics) to project the concentration- time profiles of benralizumab and the dynamics of blood eosinophils in children from 2 years to less than 12 years of age with EG/EGE Study 5 Extrapolation study to evaluate the use of benralizumab in the treatment of eosinophilic gastritis and/or

		eosinophilic gastroenteritis (EG/ EGE) in children from 2 years to less than 12 years of age.
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:	30/06/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes