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-100737-PIP01-22

Scope of the Application

Active Substance(s)

Clazakizumab

Condition(s)

Prevention and treatment of rejection of transplanted kidney

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

CSL Behring GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, CSL Behring GmbH submitted to the licensing authority on 10/11/2022 14:04 GMT an application for a Paediatric Investigation Plan

The procedure started on 27/03/2023 10:08 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-100737-PIP01-22

Of 12/04/2023 07:11 BST

On the adopted decision for Clazakizumab (MHRA-100737-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 Clazakizumab, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to CSL Behring GmbH, Emil-von-Behring-Strasse 76, Marburg, GERMANY, 35041

ANNEX I

1. Waiver

1.1 Condition:

Prevention and treatment of rejection of transplanted kidney 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 disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention and treatment of rejection of transplanted kidney

2.2 Indication(s) targeted by the PIP:

Treatment of chronic active antibody mediated rejection (AMR) in kidney transplantation

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	1	Study 1 Development of a weight-appropriate vial fill size for children below a body weight of 40 kg.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 (CSL300_XXXX) Open-label, single-arm trial to evaluate pharmacokinetics and safety of clazakizumab in children from 2 years to less than 18 years of age with chronic active antibody-mediated rejection (AMR) following kidney transplant.
Extrapolation, Modeling & Simulation Studies	2	Study 3 (CSL300_YYYY) Population PK/PD model of clazakizumab in adults with chronic active AMR following kidney transplant, supporting dose selection for Part A of Study 2. Study 4 (CSL300_WXYZ) Population PK/PD model of clazakizumab in adults and in children with a body weight from 40 kg (Cohort Part A of Study 2) with chronic active AMR following kidney transplant, supporting dose selection for Part B of Study 2.
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:	31/01/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes