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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept of change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100550-PIP01-22-M01

Scope of the Application

Active Substance(s)

BELIMUMAB

Condition(s)

Treatment of systemic lupus erythematosus

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

GlaxoSmithKline UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GlaxoSmithKline UK Limited submitted to the licensing authority on 10/06/2022 12:46 BST an application for a Modification

The procedure started on 31/01/2023 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 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100550-PIP01-22-M01

Of 06/03/2023 20:33 GMT

On the adopted decision for BELIMUMAB (MHRA-100550-PIP01-22-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

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

This decision is addressed to GlaxoSmithKline UK Limited , 980 Great West Road Brentford TW89GS, UK , Brentford, UNITED KINGDOM, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Treatment systemic lupus erythematosus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 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):

Treatment systemic lupus erythematosus

2.2 Indication(s) targeted by the PIP:

Treatment systemic lupus erythematosus

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

The paediatric population from 5 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, BEL114055 This study is the same as Study 1 (BEL114055) of the adopted belimumab UK-PIP EMEA-000520-PIP01-08-M03 for the IV formulation, P/254/2009 of 23 September 2013 and subsequent modifications thereof. Multicentre randomised, placebo-controlled, double-blind study to evaluate the safety, pharmacokinetics, and efficacy of belimumab (powder for concentrate for solution for infusion, intravenous use) in paediatric patients from 5 to less than 18 years of age with active systemic lupus erythematosus. Study 2, 200908 Open-label, multi-centre study to assess pharmacokinetics, pharmacodynamics and safety of belimumab (solution for injection, subcutaneous use) in paediatric patients from 5 to less than 18 years of age with active systemic lupus erythematosus.
Extrapolation, Modeling & Simulation Studies	1	Study 3 Modelling/simulation study to confirm dose tested in PK/ PD study (study 2) or determine a revised dose of belimumab (solution for injection, subcutaneous use) in paediatric patients from 5 to less than 18 years of age with active systemic

		lupus erythematosus, based on a comparison of paediatric exposure with exposure requirements derived from analysing the exposure response from adult SLE SC Phase 3 trial with a population PK/PD model.
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:	30/11/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes