EMA/709280/2022

European Medicines Agency decision

P/0395/2022

of 9 September 2022

on the acceptance of a modification of an agreed paediatric investigation plan for belimumab (Benlysta), (EMEA-000520-PIP02-13-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0276/2014 issued on 28 October 2014, the decision P/0063/2015 issued on 1 April 2015, the decision P/0313/2018 issued on 12 September 2018 and the decision P/0003/2020 issued on 6 January 2020,

Having regard to the application submitted by Glaxo Group Limited on 5 April 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 July 2022, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for belimumab (Benlysta), solution for injection, subcutaneous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0224/2013 issued on 23 September 2013, including subsequent modifications thereof.

Article 3

This decision is addressed to Glaxo Group Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS – London, United Kingdom.

EMA/PDCO/214343/2022 Corr
Amsterdam, 22 July 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000520-PIP02-13-M04

Scope of the application

Active substance(s):

Belimumab

Invented name:

Benlysta

Condition(s):

Treatment of systemic lupus erythematosus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Glaxo Group Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Glaxo Group Limited submitted to the European Medicines Agency on 05 April 2022 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines

Agency's decision P/0276/2014 issued on 28 October 2014, the decision P/0063/2015 issued on 1 April 2015, the decision P/0313/2018 issued on 12 September 2018 and the decision P/0003/2020 issued on 6 January 2020.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 23 May 2022.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition

Treatment of systemic lupus erythematosus

The waiver applies to:

- children from birth to less than 5 years of age;
- solution for injection, subcutaneous use;
- 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

Treatment of systemic lupus erythematosus

2.1.1. Indication(s) targeted by the PIP

Treatment of systemic lupus erythematosus

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 5 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** *This study is the same as Study 1 (BEL114055) of the belimumab 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** 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 (200908).
Extrapolation, modelling and simulation studies	**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 analyzing the exposure response from adult SLE SC Phase 3 trial with a population PK/PD model.
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By November 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Treatment of systemic lupus erythematosus

Authorised indication(s):

- Intravenous use: Benlysta is indicated as add-on therapy in patients aged 5 years and older with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g., positive anti-dsDNA and low complement) despite standard therapy.
- Subcutaneous use: Benlysta is indicated as add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy.

Authorised pharmaceutical form(s)

- Powder for concentrate for solution for infusion
- Solution for injection

Authorised route(s) of administration

- Intravenous use
- Subcutaneous use