EMA/871488/2022

European Medicines Agency decision

P/0490/2022

of 2 December 2022

on the acceptance of a modification of an agreed paediatric investigation plan for brodalumab (Kyntheum), (EMEA-001089-PIP02-13-M03) 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/0235/2014 issued on 8 September 2014, decision P/0189/2018 issued on 17 July 2018, and decision P/0386/2021 issued on 8 September 2021,

Having regard to the application submitted by LEO Pharma A/S on 27 June 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 14 October 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 and to the deferral.

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

[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 brodalumab (Kyntheum), solution for injection, subcutaneous use, including changes to the deferral, 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 is addressed to LEO Pharma A/S, Industriparken 55, 2750 – Ballerup, Denmark.

EMA/PDCO/657766/2022
Amsterdam, 14 October 2022

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

EMEA-001089-PIP02-13-M03

Scope of the application

Active substance(s):

Brodalumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of psoriasis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

LEO Pharma A/S

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, LEO Pharma A/S submitted to the European Medicines Agency on 27 June 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/0235/2014 issued on 8 September 2014, decision P/0189/2018 issued on 17 July 2018, and decision P/0386/2021 issued on 8 September 2021.

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

The procedure started on 16 August 2022.

Scope of the modification

Some measures and timelines 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 and to the deferral in the scope set out in the Annex I of this opinion.
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 psoriasis

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

2. Paediatric investigation plan

2.1. Condition:

Treatment of psoriasis

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic moderate to severe plaque psoriasis

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

From 6 years 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	**Study 1** Development of a solution for injection in a prefilled syringe.
Non-clinical studies	Not applicable.
Clinical studies	**Study 2** Study deleted with EMEA-001089-PIP02-13-M01. **Study 3** Randomized, double-blind until week 12, placebo and, active comparator (ustekinumab, open label) - controlled multicentre study to determine safety and efficacy and pharmacokinetics of brodalumab in paediatric subjects from 12 years to less than 18 years of age with moderate to severe plaque psoriasis.

	Study 4 Single-arm, open-label study with brodalumab to determine safety, efficacy and pharmacokinetics in children (age 6 years to less than 12 years) with moderate to severe plaque psoriasis.
Extrapolation, modelling and simulation studies	**Study 5** Population modelling and simulation of the pharmacokinetic of brodalumab study to support the choice of dose and dosing regime in Study 4.
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 February 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s):

1. Treatment of psoriasis

Authorised indication(s):

- Kyntheum is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Subcutaneous injection