EMA/287810/2023 Corr[1]

European Medicines Agency decision

P/0049/2023

of 14 July 2023

on the acceptance of a modification of an agreed paediatric investigation plan for ixekizumab (Taltz), (EMEA-001050-PIP02-18-M02) 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.

[1] Corrigendum 25 April 2024

European Medicines Agency decision

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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[2],

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[3],

Having regard to the European Medicines Agency's decision P/0352/2018 issued on 20 November 2018 and the decision P/0280/2019 issued on 16 August 2019,

Having regard to the application submitted by Eli Lilly and Company (Ireland) Limited on 20 February 2023 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 26 May 2023, 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.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for ixekizumab (Taltz), 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0090/2012 issued on 29/5/2012, including subsequent modifications thereof.

Article 3

This decision is addressed to Eli Lilly and Company (Ireland) Limited, Dunderrow, P17 NA72 - Kinsale, County Cork, Ireland.

EMA/PDCO/87066/2023
Amsterdam, 26 May 2023

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

EMEA-001050-PIP02-18-M02

Scope of the application

Active substance(s):

Ixekizumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Eli Lilly and Company (Ireland) Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company (Ireland) Limited submitted to the European Medicines Agency on 20 February 2023 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/0352/2018 issued on 20 November 2018. and the decision P/0280/2019 issued on 16 August 2019.

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

The procedure started on 27 March 2023.

Scope of the modification

Some 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.

   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 chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

The waiver applies to:

- the paediatric population from birth to less than 2 year 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 chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

2.1.1. Indication(s) targeted by the PIP

Treatment of juvenile idiopathic arthritis (JIA) subsets of Juvenile enthesitis-related arthritis (ERA) including juvenile onset ankylosing spondylitis (JoAS) and juvenile psoriatic arthritis JPsA in paediatric patients from the age of 2 years.

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Studies

Area	**Description**
Quality	**Study 1** Development of prefilled syringe presentations to accommodate weight strata subcutaneous (SC) dosing in children
Non-clinical	**Study 2** Repeat-Dose Fertility Study to investigate the potential effects of ixekizumab

	Study 3 PPND Toxicity Study to evaluate development of the F1 offspring, including the immune system, following in utero exposure to ixekizumab
Clinical	**Study 4** Open label, efficacy, safety, tolerability, pharmacokinetic study of subcutaneous ixekizumab with adalimumab reference arm in children with juvenile idiopathic arthritis subtypes of enthesitis-related arthritis (including juvenile-onset ankylosing spondylitis) and juvenile psoriatic arthritis.
Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By July 2024
Deferral for one or more studies 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):

- Plaque psoriasis

  Taltz is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

  - Invented name(s): Taltz
  - Authorised pharmaceutical form(s): Solution for injection in pre-filled syringe
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure

- Paeditric plaque psoriasis

  Taltz is indicated for the treatment of moderate to severe plaque psoriasis in children from the age of 6 years and with a body weight of at least 25 kg and adolescents who are candidates for systemic therapy.

  - Invented name(s): Taltz
  - Authorised pharmaceutical form(s): Solution for injection in pre-filled syringe
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure

- Psoriatic arthritis

  Taltz, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies.

  - Invented name(s): Taltz
  - Authorised pharmaceutical form(s): Solution for injection in pre-filled syringe
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure

- Axial spondyloarthritis

  Taltz is indicated for the treatment of adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy.

  - Invented name(s): Taltz
  - Authorised pharmaceutical form(s): Solution for injection in pre-filled syringe
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure

- Non-radiographic axial spondyloarthritis

  Taltz is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs)

  - Invented name(s): Taltz
  - Authorised pharmaceutical form(s): Solution for injection in pre-filled syringe
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure