EMA/576562/2016

European Medicines Agency decision

P/0233/2016

of 9 September 2016

on the acceptance of a modification of an agreed paediatric investigation plan for ixekizumab (Taltz), (EMEA-001050-PIP01-10-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.

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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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0090/2012 issued on 29 May 2012 and the decision P/0100/2016 issued on 15 April 2016,

Having regard to the application submitted by Eli Lilly & Company Limited on 29 April 2016 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 2016, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for ixekizumab (Taltz), 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 is addressed to Eli Lilly & Company Limited, Research Centre Erl Wood Manor, Sunninghill Road, Windlesham - GU20 6PH, United Kingdom.

EMA/PDCO/340968/2016 Corr
London, 22 July 2016

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

EMEA-001050-PIP01-10-M02

Scope of the application

Active substance(s):

Ixekizumab

Invented name:

Taltz

Condition(s):

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

Treatment of psoriasis

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:

Eli Lilly & Company Limited

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eli Lilly & Company Limited submitted to the European Medicines Agency on 29 April 2016 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/0090/2012 issued on 29 May 2012 and the decision P/0100/2016 issued on 15 April 2016.

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

The procedure started on 24 May 2016.

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 in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member 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 1 year of age;
- for 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).

1.2. Condition

Treatment of psoriasis

The waiver applies to:

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

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 JIA (including polyarticular arthritis, extended oligoarticular arthritis, sJIA without active systemic features, and ERA including JoAS and JPsA) in paediatric patients from the age of 2 years

Treatment of sJIA with active systemic features in paediatric patients from the age of 1 year

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

From 1 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1** Development of prefilled syringe presentations to accommodate weight strata subcutaneous (SC) dosing in children
Non-clinical	2	**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	2	**Study 4** Multicentre, double-blind, randomized, placebo-controlled, safety, tolerability, pharmacokinetic and efficacy study of subcutaneous Ixekizumab in children with juvenile idiopathic arthritis **Study 5** Multicentre, double-blind, randomized, placebo-controlled, safety, tolerability, PK, and efficacy study of Ixekizumab in children with systemic juvenile idiopathic arthritis with active systemic features (sJIA)
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	Not applicable

2.2. Condition

Treatment of psoriasis

2.2.1. Indication(s) targeted by the PIP

Treatment of psoriasis

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

From 6 to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Solution for injection

2.2.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1** As per condition 2.1
Non-clinical	2	**Study 2** As per condition 2.1 **Study 3** As per condition 2.1
Clinical	1	**Study 6 (I1F-MC-RHCD)** Multicentre, double-blind, randomized, active- and placebo-controlled study to evaluate safety, tolerability, and efficacy of Ixekizumab in patients from 6 to less than 18 years of age with plaque psoriasis

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 October 2025
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of psoriasis

Authorised indication(s):

- Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Authorised pharmaceutical form(s):

Solution for injection in pre-filled syringe

Authorised route(s) of administration:

Subcutaneous