



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/591155/2014

European Medicines Agency decision

P/0268/2014

of 27 October 2014

on the acceptance of a modification of an agreed paediatric investigation plan for tabalumab (EMA-000802-PIP02-11-M01) 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.



European Medicines Agency decision

P/0268/2014

of 27 October 2014

on the acceptance of a modification of an agreed paediatric investigation plan for tabalumab (EMA-000802-PIP02-11-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0100/2012 issued on 30 May 2012,

Having regard to the application submitted by Eli Lilly and Company Limited on 6 June 2014 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 12 September 2014, 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 tabalumab, 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 and Company Limited, Erl Wood Manor, Sunninghill Road, GU20 6PH - Windlesham, United Kingdom.

Done at London, 27 October 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/395031/2014

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

EMA-000802-PIP02-11-M01

Scope of the application

Active substance(s):

Tabalumab

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:

Eli Lilly and Company Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company Limited submitted to the European Medicines Agency on 6 June 2014 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/0100/2012 issued on 30 May 2012.

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

The procedure started on 16 July 2014.

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 Icelandic and the Norwegian Paediatric Committee members agree 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 annex and appendix.

London, 12 September 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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;
- 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).

2. Paediatric Investigation Plan

2.1. Condition: Treatment of systemic lupus erythematosus

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients from 5 to less than 18 years old with active, autoantibody-positive systemic lupus erythematosus with a high degree of disease activity despite standard therapy.

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	Number of studies	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	1	Study 1 Pre and post natal developmental toxicity study in cynomolgus monkeys including immunotoxicology assessment of the F1 offspring.
Clinical studies	1	Study 3 Multicentre, double-blind, randomised, placebo-controlled withdrawal study for evaluation of efficacy, safety and pharmacokinetics of anti-BAFF monoclonal antibody in patients with paediatric systemic lupus erythematosus.
Extrapolation,	0	Not applicable.

Area	Number of studies	Description
modelling and simulation studies		
Other studies	0	Not applicable.
Other measures	0	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 March 2021
Deferral for one or more studies contained in the paediatric investigation plan:	Yes