EMA/104672/2017

European Medicines Agency decision

P/0055/2017

of 17 March 2017

on the acceptance of a modification of an agreed paediatric investigation plan for tofacitinib (EMEA-000576-PIP02-11-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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

An agency of the European Union

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on the acceptance of a modification of an agreed paediatric investigation plan for tofacitinib (EMEA-000576-PIP02-11-M04) 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 726/2004[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/0257/2012 issued on 26 October 2012, the decision P/0170/2013 issued on 30 July 2013, the decision P/0036/2014 issued on 5 March 2014 and the decision P/0216/2014 issued on 3 September 2014,

Having regard to the application submitted by Pfizer Limited on 7 November 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 27 January 2017, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for tofacitinib, film-coated tablet, oral solution, oral 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 Pfizer Limited, Ramsgate Road, CT13 9NJ - Sandwich, United Kingdom.

EMA/PDCO/733478/2016
London, 27 January 2017

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

EMEA-000576-PIP02-11-M04

Scope of the application

Active substance(s):

Tofacitinib

Condition(s):

Treatment of psoriasis

Pharmaceutical form(s):

Film-coated tablet

Oral solution

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Pfizer Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Limited submitted to the European Medicines Agency on 7 November 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/0257/2012 issued on 26 October 2012, the decision P/0170/2013 issued on 30 July 2013, the decision P/0036/2014 issued on 5 March 2014 and the decision P/0216/2014 issued on 3 September 2014.

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

The procedure started on 29 November 2016.

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 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 annex 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;
- film-coated tablet, oral solution, oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric investigation plan

2.1. Condition

Treatment of psoriasis

2.1.1. Indication(s) targeted by the PIP

Treatment of severe plaque psoriasis

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Oral solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of age appropriate oral liquid formulation. Development of an appropriate administering device (e.g. oral syringe with suitable graduation).
Non-clinical studies	2	**Study 2** (09GR248) Toxicity study in juvenile cynomolgous monkeys. **Study 3** (10GR307) Oral toxicity study of tofacitinib in juvenile rats.

Clinical studies	1	**Study 4** Randomised, double-blind, placebo controlled study to evaluate efficacy and safety of tofacitinib in paediatric subjects with psoriasis from 6 to less than 18 years of age.
Extrapolation, modelling and simulation studies	3	**Study 5** Population PK and exposure-response model in adult psoriasis patients. **Study 6** A population PK model in paediatric psoriasis patients. **Study 7** Extrapolation of PK characteristics for determining starting dose in adolescents (from 12 to less than 17 years of age) and children (from 6 to less than 12 years of age).
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 December 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes