EMA/90866/2017

European Medicines Agency decision

P/0054/2017

of 17 March 2017

on the acceptance of a modification of an agreed paediatric investigation plan for tofacitinib (EMEA-000576-PIP01-09-M06) 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

European Medicines Agency decision

P/0054/2017

of 17 March 2017

on the acceptance of a modification of an agreed paediatric investigation plan for tofacitinib (EMEA-000576-PIP01-09-M06) 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/144/2010 issued on 30 July 2010, the decision P/162/2011 issued on 4 July 2011, the decision P/0064/2012 issued on 28 March 2012, the decision P/0169/2013 issued on 30 July 2013, the decision P/0035/2014 issued on 5 March 2014 and the decision P/0013/2015 issued on 30 January 2015,

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.

(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 tofacitinib, film-coated tablet, oral solution, oral 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 Pfizer Limited, Ramsgate Road, CT13 9NJ - Sandwich, United Kingdom.

EMA/PDCO/757359/2016
London, 27 January 2017

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

EMEA-000576-PIP01-09-M06

Scope of the application

Active substance(s):

Tofacitinib

Condition(s):

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

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/144/2010 issued on 30 July 2010, the decision P/162/2011 issued on 4 July 2011, the decision P/0064/2012 issued on 28 March 2012, the decision P/0169/2013 issued on 30 July 2013, the decision P/0035/2014 issued on 5 March 2014 and the decision P/0013/2015 issued on 30 January 2015.

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

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

The waiver applies to:

- children from birth to less than 2 years;
- for film-coated tablet, oral solution, for oral 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 spondylitis and juvenile idiopathic arthritis)

2.1.1. Indication targeted by the PIP

Treatment of juvenile idiopathic arthritis (extended oligoarthritis, RF+ polyarthritis, RF- polyarthritis, enthesitis related arthritis, psoriatic arthritis, systemic JIA).

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

Film-coated tablet, oral solution.

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	**Study 1** Development of age appropriate oral liquid formulation
Non-clinical studies	3	**Study 2** Juvenile non-human primate 39 week toxicology study followed by 26 week recovery period **Study 3** Juvenile rat 1 month toxicity study followed by 2 months recovery

		Study 4 Juvenile rat fertility study for 50 days in males and 35 days in females
Clinical studies	3	**Study 5** Multiple dose pharmacokinetic study in children from 2 to less than 18 years of age with juvenile idiopathic arthritis **Study 6** Randomised withdrawal double blind placebo controlled study to evaluate efficacy and safety of CP-690,550 in children from 2 to less than 18 years old with polyarticular course juvenile idiopathic arthritis (i.e. extended oligoarthritis, RF+/RF- polyarthritis and systemic arthritis without systemic features), enthesitis related arthritis and psoriatic arthritis **Study 7** Randomised double blind placebo controlled study to evaluate safety and efficacy of CP-690,550 in children from 2 to less than 18 years old with systemic juvenile idiopathic arthritis with active systemic features
Extrapolation, modelling and simulation studies		Not applicable.
Other studies		Not applicable.
Other measures		Not applicable.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By August 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes