EMA/710588/2018

European Medicines Agency decision

P/0372/2018

Of 7 December 2018

on the acceptance of a modification of an agreed paediatric investigation plan for secukinumab (Cosentyx), (EMEA-000380-PIP02-09-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

European Medicines Agency decision

P/0372/2018

Of 7 December 2018

on the acceptance of a modification of an agreed paediatric investigation plan for secukinumab (Cosentyx), (EMEA-000380-PIP02-09-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/141/2010 issued on 30 July 2010, the decision P/0002/2014 issued on 21 January 2014, the decision P/0247/2014 issued on 30 September 2014, and the decision P/0168/2016 issued on 17 June 2016,

Having regard to the application submitted by Novartis Europharm Limited on 16 July 2018 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 19 October 2018, 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 secukinumab (Cosentyx), powder for solution for injection or infusion, solution for injection, subcutaneous use, intravenous 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/154/2009 issued on 11 August 2009, including subsequent modifications thereof.

Article 3

This decision is addressed to Novartis Europharm Limited, Frimley Business Park,
GU16 7SR - Camberley, United Kingdom.

EMA/PDCO/499572/2018
London, 19 October 2018

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

EMEA-000380-PIP02-09-M04

Scope of the application

Active substance(s):

Secukinumab

Invented name:

Cosentyx

Condition(s):

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

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for injection or infusion

Solution for injection

Route(s) of administration:

Subcutaneous use

Intravenous use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 16 July 2018 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/141/2010 issued on 30 July 2010, the decision P/0002/2014 issued on 21 January 2014, the decision P/0247/2014 issued on 30 September 2014, and the decision P/0168/2016 issued on 17 June 2016.

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

The procedure started on 21 August 2018.

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 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, spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

The waiver applies to:

- children from birth to less than 2 years of age;
- for powder for solution for injection or infusion and for solution for injection for subcutaneous use and intravenous 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.

2. Paediatric Investigation Plan

2.1. Condition

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

2.1.1. Indication(s) targeted by the PIP

Treatment of juvenile idiopathic arthritis (enthesis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA)

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for solution for injection or infusion

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	**Study 1** This study was deleted as a result of procedure EMEA-000380-PIP02-09-M04.
Non-clinical studies	0	Not applicable.

Clinical studies	1	**Study 3** Double-blind, randomised, placebo controlled three-part withdrawal study to evaluate efficacy and safety of secukinumab in children with juvenile idiopathic arthritis (enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA)).
Extrapolation, modelling and simulation studies	1	**Study 2** Population pharmacokinetic modelling.
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 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of plaque psoriasis

Authorised indication(s):

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

2. Treatment of psoriatic arthritis

Authorised indication(s):

- Treatment, alone or in combination with methotrexate (MTX), of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

3. Treatment of ankylosing spondylitis

Authorised indication(s):

- Treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.

Authorised pharmaceutical form(s):

Powder for solution for injection

Solution for injection

Authorised route(s) of administration:

Subcutaneous use