EMA/530125/2023

European Medicines Agency decision

P/0492/2023

of 1 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for risankizumab (Skyrizi), (EMEA-001776-PIP02-17-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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0343/2017 issued on 23 November 2017 and the decision P/0039/2021 issued on 27 January 2021,

Having regard to the application submitted by AbbVie Ltd on 3 July 2023 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 13 October 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for Risankizumab (Skyrizi), solution for injection, age-appropriate pharmaceutical form, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0205/2016 issued on 04/08/2016, and decision P/0230/2018 issued on 03/08/2018, including subsequent modifications thereof.

Article 3

This decision is addressed to AbbVie Ltd, AbbVie House, Vanwall Road, SL6 - 4UB, Maidenhead, United Kingdom.

EMA/PDCO/315798/2023
Amsterdam, 13 October 2023

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

EMEA-001776-PIP02-17-M02

Scope of the application

Active substance(s):

Risankizumab

Invented name and authorisation status:

See Annex II

Condition(s):

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

Pharmaceutical form(s):

Solution for injection

Age-appropriate pharmaceutical form

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

AbbVie Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AbbVie Ltd submitted to the European Medicines Agency on 3 July 2023an 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/0343/2017 issued on 23 November 2017 and the decision P/0039/2021 issued on 27 January 2021.

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

The procedure started on 14 August 2023.

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 Paediatric Committee member of Norway 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, spondylarthritis and juvenile idiopathic arthritis)

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- solution for injection, age-appropriate pharmaceutical form, 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).

The waiver applies to:

- the paediatric population from 1 to less than 5 years of age;
- solution for injection, age-appropriate pharmaceutical form, subcutaneous use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric investigation plan

2.1. Condition

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

2.1.1. Indication(s) targeted by the PIP

Treatment of juvenile psoriatic arthritis (JIA PsA)

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, age-appropriate pharmaceutical form

2.1.4. Measures

Area	**Description**
Quality-related studies	**Study 1** Development of an age-appropriate pharmaceutical form
Non-clinical studies	Not applicable

Clinical studies	**Study 2 (M23-732)** Open-label, randomised, assessor-blinded trial to evaluate efficacy, safety, tolerability and pharmacokinetics (PK) study of subcutaneous risankizumab with an adalimumab reference arm in children from 5 to less than 18 years of age with juvenile psoriatic arthritis (JIA-PsA)
Extrapolation, modelling and simulation studies	**Study 3** Modelling and simulation study to predict risankizumab doses in children and adolescents from 5 to less than 18 years of age with active juvenile psoriatic arthritis (JIA-PsA)
Other studies	Not applicable.
Other measures	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By July 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

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
  - Invented name(s): Skyrizi
  - Authorised pharmaceutical form(s): solution for injection
  - Authorised route(s) of administration: subcutaneous use
  - Authorised via centralised procedure

2. Treatment of Psoriatic arthritis

Authorised indication(s):

- Skyrizi, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).
  - Invented name(s): Skyrizi
  - Authorised pharmaceutical form(s): solution for injection
  - Authorised route(s) of administration: subcutaneous use
  - Authorised via centralised procedure

3. Treatment of Crohn’s disease

Authorised indication(s):

- Treatment of adult patients with moderately to severely active Crohn’s disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy.
  - Invented name(s): Skyrizi
  - Authorised pharmaceutical form(s): concentrate for solution for infusion, solution for injection
  - Authorised route(s) of administration: intravenous use, subcutaneous use
  - Authorised via centralised procedure