EMA/412625/2023

European Medicines Agency decision

P/0391/2023

of 13 September 2023

on the acceptance of a modification of an agreed paediatric investigation plan for risankizumab (Skyrizi), (EMEA-001776-PIP04-17-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.

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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/0231/2018 issued on 3 August 2018,

Having regard to the application submitted by AbbVie Ltd on 31 August 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 8 September 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), concentrate for solution for infusion, solution for injection, age-appropriate dosage form for parenteral use, intravenous use, 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, decision P/0343/2017 issued on 23/11/2017, and decision P/0230/2018 issued on 03/08/2018, including subsequent modifications thereof), including subsequent modifications thereof.

Article 3

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

EMA/PDCO/397816/2023
Amsterdam, 8 September 2023

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

EMEA-001776-PIP04-17-M01

Scope of the application

Active substance(s):

Risankizumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of ulcerative colitis

Pharmaceutical form(s):

Concentrate for solution for infusion

Solution for injection

Age-appropriate dosage form for parenteral use

Route(s) of administration:

Intravenous use

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 31 August 2023 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/0231/2018 issued on 3 August 2018.

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

The procedure started on 1 September 2023.

Scope of the modification

Administrative modification of the decision to link this PIP with PIP decisions covering all authorised indications of risankizumab (decision P/0205/2016 for treatment of psoriasis, decision P/0343/2017 for treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, spondylarthritis and juvenile idiopathic arthritis), and decision P/0230/2018 for the treatment of Crohn's Disease, including subsequent modifications thereof).

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 ulcerative colitis

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- concentrate for solution for infusion, solution for injection, age-appropriate dosage form for parenteral use; intravenous use, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition

Treatment of ulcerative colitis

2.1.1. Indication(s) targeted by the PIP

Treatment of moderately to severely active ulcerative colitis

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)

Concentrate for solution for infusion

Solution for injection

Age-appropriate dosage form for parenteral use

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1 - Paediatric formulation 1** Development of an age-appropriate paediatric formulation/presentation for paediatric use for induction treatment **Study 2 - Paediatric formulation 2** Development of an age-appropriate paediatric formulation/presentation for paediatric use for maintenance treatment

Non-clinical studies	Not applicable
Clinical studies	**Study 3** Open-label study in paediatric patients with ulcerative colitis (UC) to evaluate the efficacy, safety, and pharmacokinetics (PK) of risankizumab
Extrapolation, modelling and simulation studies	**Study 4** Modelling and simulation population PK study
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 December 2028
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 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):

- Treatment – alone or in combination with methotrexate (MTX) - of adult patients with active psoriatic arthritis 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