EMA/351176/2023 Corr[1]

European Medicines Agency decision

P/0376/2023

of 8 September 2023

on the acceptance of a modification of an agreed paediatric investigation plan for risankizumab (Skyrizi), (EMEA-001776-PIP03-17-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.

[1] 19 September 2023

European Medicines Agency decision

P/0376/2023

of 8 September 2023

on the acceptance of a modification of an agreed paediatric investigation plan for risankizumab (Skyrizi), (EMEA-001776-PIP03-17-M01) 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[2],

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[3],

Having regard to the European Medicines Agency's decision P/0230/2018 issued on 3 August 2018,

Having regard to the application submitted by AbbVie Ltd on 4 April 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 21 July 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 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.

[2] OJ L 378, 27.12.2006, p.1, as amended.
[3] 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, 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 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 the decision P/0343/2017 issued on 23/11/2017, including subsequent modifications thereof.

Article 3

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

EMA/PDCO/202487/2023
Amsterdam, 21 July 2023

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

EMEA-001776-PIP03-17-M01

Scope of the application

Active substance(s):

Risankizumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of Crohn's disease

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 4 April 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/0230/2018 issued on 3 August 2018.

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

The procedure started on 22 May 2023.

Scope of the modification

Some measures and 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 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 Crohn's Disease

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- 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 Crohn's Disease

2.1.1. Indication(s) targeted by the PIP

Treatment of moderately to severely active Crohn's disease

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(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** Development of an age-appropriate paediatric formulation/presentation for paediatric use for induction treatment **Study 2** Development of an age-appropriate paediatric formulation/presentation for paediatric use for maintenance treatment
Non-clinical studies	Not applicable

Clinical studies	**Study 3** Study in paediatric patients from 2 years to less than 18 years of age with Crohn's disease (CD) to evaluate the efficacy, safety, and pharmacokinetics (PK) of risankizumab including a 12- week open label induction period followed by a randomised 52-week maintenance period.
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 March 2029
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 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