

EMA/532352/2021

European Medicines Agency decision P/0454/2021

of 29 October 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for adalimumab conjugated with (4S)-4-[2-(2-bromoacetamido)acetamido]-5-{3-[(4- {(4aR,4bS,5S,6aS,6bS,8R,9aR,10aS,10bS)-5-hydroxy-4a,6a-dimethyl-2-oxo-6b-[(phosphonoxy)acetyl]-4a,4b,5,6,6a,6b,9a,10,10a,10b,11,12-dodecahydro-2H,8Hnaphtho[2',1':4,5]indeno[1,2-d][1,3]dioxol-8-yl}phenyl)methyl] anilino}-5-oxopentanoic acid; (ABBV- 154) (EMA-002927-PIP01-20) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by AbbVie Ltd on 26 November 2020 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 September 2021, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for adalimumab conjugated with (4S)-4-[2-(2-bromoacetamido)acetamido]-5-{3-[(4-{(4aR,4bS,5S,6aS,6bS,8R,9aR,10aS,10bS)-5-hydroxy-4a,6a-dimethyl-2-oxo-6b-[(phosphonooxy)acetyl]-4a,4b,5,6,6a,6b,9a,10,10a,10b,11,12-dodecahydro-2H,8Hnaphtho[2',1':4,5]indeno[1,2-d][1,3]dioxol-8-yl}phenyl)methyl] anilino}-5-oxopentanoic acid; (ABBV- 154), solution for injection (in pre-filled syringe), subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for adalimumab conjugated with (4S)-4-[2-(2-bromoacetamido)acetamido]-5-{3-[(4-{(4aR,4bS,5S,6aS,6bS,8R,9aR,10aS,10bS)-5-hydroxy-4a,6a-dimethyl-2-oxo-6b-[(phosphonooxy)acetyl]-4a,4b,5,6,6a,6b,9a,10,10a,10b,11,12-dodecahydro-2H,8Hnaphtho[2',1':4,5]indeno[1,2-d][1,3]dioxol-8-yl}phenyl)methyl] anilino}-5-oxopentanoic acid; (ABBV- 154), solution for injection (in pre-filled syringe), subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for adalimumab conjugated with (4S)-4-[2-(2-bromoacetamido)acetamido]-5-{3-[(4-{(4aR,4bS,5S,6aS,6bS,8R,9aR,10aS,10bS)-5-hydroxy-4a,6a-dimethyl-2-oxo-6b-[(phosphonooxy)acetyl]-4a,4b,5,6,6a,6b,9a,10,10a,10b,11,12-dodecahydro-2H,8Hnaphtho[2',1':4,5]indeno[1,2-d][1,3]dioxol-8-yl}phenyl)methyl] anilino}-5-oxopentanoic acid; (ABBV- 154), solution for injection (in pre-filled syringe), subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

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

EMA/PDCO/350122/2021
Amsterdam, 10 September 2021

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-002927-PIP01-20

Scope of the application

Active substance(s):

Adalimumab conjugated with (4S)-4-[2-(2-bromoacetamido)acetamido]-5-{3-[(4-{(4aR,4bS,5S,6aS,6bS,8R,9aR,10aS,10bS)-5-hydroxy-4a,6a-dimethyl-2-oxo-6b-[(phosphonoxy)acetyl]-4a,4b,5,6,6a,6b,9a,10,10a,10b,11,12-dodecahydro-2H,8H-naphtho[2',1':4,5]indeno[1,2-d][1,3]dioxol-8-yl}phenyl)methyl] anilino}-5-oxopentanoic acid; (ABBV-154)

Condition(s):

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

Pharmaceutical form(s):

Solution for injection (in pre-filled syringe)

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

AbbVie Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, AbbVie Ltd submitted for agreement to the European Medicines Agency on 26 November 2020 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 4 January 2021.

Supplementary information was provided by the applicant on 3 June 2021.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
 - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
 - to grant a deferral in accordance with Article 21 of said Regulation;
 - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population; and with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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:

- the paediatric population from birth to less than 1 year of age;
- Solution for injection (in pre-filled syringe), 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).

and to:

- the paediatric population from 1 year to less than 2 years of age;
- Solution for injection (in pre-filled syringe), 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 chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis)

2.1.1. Indication(s) targeted by the PIP

Treatment of juvenile idiopathic arthritis (polyarthritis rheumatoid factor (RF) positive and RF negative, persistent and extended oligoarthritis, and enthesitis-related arthritis (ERA))

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)

Solution for injection (in pre-filled syringe)

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Development of age-appropriate dose strength

Non-clinical studies	1	Study 2 Enhanced pre- and postnatal development (ePPND) study in monkeys
Clinical studies	1	Study 3 Double-blind, randomised, active controlled trial with an open-label pharmacokinetics (PK) lead-in part to evaluate PK, efficacy and safety of ABBV-154 in children and adolescents from 2 years to less than 18 years of age with juvenile idiopathic arthritis (JIA). A separate open-label part will be open to children and adolescents from 2 years to less than 18 years of age with JIA-associated uveitis or chronic anterior antinuclear antibody-positive (ANA-positive) uveitis.
Extrapolation, modelling and simulation studies	1	Study 4 Modelling and simulation study to support dose selection and confirmation of ABBV-154 for the paediatric Study 3 in children and adolescents from 2 years to less than 18 years of age with juvenile idiopathic arthritis (JIA).
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:	No
Date of completion of the paediatric investigation plan:	By March 2034
Deferral for one or more measures contained in the paediatric investigation plan:	Yes