MHRA
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Canary Wharf
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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100226-PIP01-21

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-[(phosphonooxy)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 (rheumatoid, psoriatic, JIA, ankylosing spondylitis)

Pharmaceutical Form(s)

Solution for injection (in a pre-filled syringe)

Route(s) of Administration

Subcutaneous use

Name / Corporate name of the PIP applicant

AbbVie Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AbbVie Ltd submitted to the licensing authority on 13/09/2021 16:33 BST an application for a Paediatric Investigation Plan

The procedure started on 19/05/2022 15:08 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a deferral and grant a waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100226-PIP01-21

Of 24/06/2022 16:11 BST

On the adopted decision 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,8H-naphtho[2',1':4,5]indeno[1,2-d][1,3]dioxol-8-yl}phenyl)methyl] anilino}-5-oxopentanoic acid; ABBV-154 (MHRA-100226-PIP01-21) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to 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,8H-naphtho[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 a pre-filled syringe) , Subcutaneous use .

This decision is addressed to AbbVie Ltd, Vanwall Business Park, Vanwall Road, Maidenhead, United Kingdom, SL6 4UB

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Solution for injection (in a pre-filled syringe) Route(s) of administration: Subcutaneous use Reason for granting waiver: For the paediatric population from birth to less than 1 year of age: 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). For the paediatric population from 1 year to less than 2 years of age: 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(s):

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

2.2 Indication(s) targeted by the PIP:

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

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection (in a pre-filled syringe)

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate dose strength.
Non-Clinical Studies	1	Study 2 Enhanced pre- and post-natal 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, Modeling & 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 a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/03/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes