



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/662865/2022

European Medicines Agency decision P/0269/2022

of 11 August 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for (1R,2R)-2-[4-(5-methyl-1H-pyrazol-3-yl) benzoyl]-N-(4-oxo-6,7-dihydro-5H-pyrazolo [1,5-a]pyrazin-3-yl)cyclohexanecarboxamide (AZD5718)(EMA-003098-PIP01-21) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency²,

Having regard to the application submitted by AstraZeneca AB on 9 September 2021 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 24 June 2022, 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, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for (1R,2R)-2-[4-(5-methyl-1H-pyrazol-3-yl) benzoyl]-N-(4-oxo-6,7-dihydro-5H-pyrazolo [1,5-a]pyrazin-3-yl)cyclohexanecarboxamide (AZD5718), tablet, age-appropriate oral solid dosage form, film-coated tablet, oral 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 (1R,2R)-2-[4-(5-methyl-1H-pyrazol-3-yl) benzoyl]-N-(4-oxo-6,7-dihydro-5H-pyrazolo [1,5-a]pyrazin-3-yl)cyclohexanecarboxamide (AZD5718), tablet, age-appropriate oral solid dosage form, film-coated tablet, oral 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 (1R,2R)-2-[4-(5-methyl-1H-pyrazol-3-yl) benzoyl]-N-(4-oxo-6,7-dihydro-5H-pyrazolo [1,5-a]pyrazin-3-yl)cyclohexanecarboxamide (AZD5718), tablet, age-appropriate oral solid dosage form, film-coated tablet, oral 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 AstraZeneca AB, SE-151 85 - Södertälje, Sweden.

EMA/PDCO/204301/2022
Amsterdam, 24 June 2022

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

EMA-003098-PIP01-21

Scope of the application

Active substance(s):

(1R,2R)-2-[4-(5-methyl-1H-pyrazol-3-yl) benzoyl]-N-(4-oxo-6,7-dihydro-5H-pyrazolo [1,5-a]pyrazin-3-yl)cyclohexanecarboxamide (AZD5718)

Condition(s):

Treatment of proteinuric chronic kidney disease

Pharmaceutical form(s):

Tablet

Age-appropriate oral solid dosage form

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted for agreement to the European Medicines Agency on 9 September 2021 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 19 October 2021.

Supplementary information was provided by the applicant on 17 March 2022. The applicant proposed modifications to the paediatric investigation plan.

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.

The Paediatric Committee member of Norway 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 proteinuric chronic kidney disease

The waiver applies to:

- the paediatric population from birth to less than 3 months of age;
- tablet, age-appropriate oral solid dosage form, film-coated tablet, oral 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).

2. Paediatric investigation plan

2.1. Condition:

Treatment of proteinuric chronic kidney disease

2.1.1. Indication(s) targeted by the PIP

Treatment of proteinuric chronic kidney disease

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 3 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Tablet

Age-appropriate oral solid dosage form

Film-coated tablet

2.1.4. Measures

Area	Description
Quality-related studies	Study 1: Development of age-appropriate oral solid dosage form for children below 6 years of age
Non-clinical studies	Not applicable.
Clinical studies	Study 2: Double-blind, placebo-controlled, randomised trial to evaluate safety, efficacy and pharmacokinetics of AZD5718 in children from 3 months to less than 18 years of age with proteinuric chronic kidney disease

Extrapolation, modelling and simulation studies	Study 3: Modelling and simulation study for paediatric dose selection to evaluate the use of AZD5718 in children from 3 months to less than 18 years of age with proteinuric chronic kidney disease
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 2034
Deferral for one or more measures contained in the paediatric investigation plan:	Yes