



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-2022970

European Medicines Agency decision

EMA/PE/0000232774

of 16 April 2025

on the agreement of a paediatric investigation plan and on the granting of a deferral for 7-fluoro-1-isopropyl-3-methyl-8-(6-(3-(piperidin-1-yl)propoxy)pyridin-3-yl)-1,3-dihydro-2H-imidazo[4,5-c]quinolin-2-one (AZD1390) () 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.



European Medicines Agency decision

EMA/PE/0000232774

of 16 April 2025

on the agreement of a paediatric investigation plan and on the granting of a deferral for 7-fluoro-1-isopropyl-3-methyl-8-(6-(3-(piperidin-1-yl)propoxy)pyridin-3-yl)-1,3-dihydro-2H-imidazo[4,5-c]quinolin-2-one (AZD1390) 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 726/2004¹,

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 25 April 2024 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 28 February 2025, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 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.
- (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.

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 7-fluoro-1-isopropyl-3-methyl-8-(6-(3-(piperidin-1-yl)propoxy)pyridin-3-yl)-1,3-dihydro-2H-imidazo[4,5-c]quinolin-2-one (AZD1390), 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 7-fluoro-1-isopropyl-3-methyl-8-(6-(3-(piperidin-1-yl)propoxy)pyridin-3-yl)-1,3-dihydro-2H-imidazo[4,5-c]quinolin-2-one (AZD1390) (), 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

This decision is addressed to AstraZeneca AB, 151 85 - Sodertalje, Sweden.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1805565

Amsterdam, 28 February 2025

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

EMA/PE/0000232774

Scope of the application

Active substance(s):

7-fluoro-1-isopropyl-3-methyl-8-(6-(3-(piperidin-1-yl)propoxy)pyridin-3-yl)-1,3-dihydro-2H-imidazo[4,5-c]quinolin-2-one (AZD1390)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of malignant neoplasms of the central nervous system

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral dosage form

Route(s) of administration:

Oral use

Gastric 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 25 April 2024 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 27 May 2024.



Supplementary information was provided by the applicant on 22 November 2024. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

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.

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 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of malignant neoplasms of the central nervous system

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients from birth to less than 18 years of age with newly diagnosed high-grade glioma or diffuse intrinsic pontine glioma.

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate oral dosage form

2.1.4. Measures

Area	Description
Quality-related studies	Study 1 Generation of data on the appropriateness of dispersing the existing film-coated tablet with food and drinks for oral use of AZD1390 in paediatric participants unable to swallow film-coated tablets as whole. Study 2 Development of an age-appropriate formulation of AZD1390 for oral use in the paediatric population from birth.
Non-clinical studies	Not applicable
Clinical studies	Study 3 Open-label, single-arm trial to evaluate the pharmacokinetics, safety, tolerability and anti-tumour activity and to identify the recommended phase 2 dose of AZD1390 used in combination with focal radiotherapy in children from birth to less than 18 years of age with newly diagnosed high-grade glioma or diffuse intrinsic pontine glioma (dose-finding part) and to determine the safety and antitumour activity of the recommended phase 2 dose of

	<p>AZD1390 used in combination with radiotherapy (expansion part). For the age group from birth to less than 1 year of age, only patients with H3-mutated high-grade glioma to be recruited.</p> <p>Study 4</p> <p>Open-label, randomised, controlled trial to evaluate the efficacy and safety of AZD1390 used in combination with focal radiotherapy compared to best known standard of care, in participants from birth to less than 18 years of age with newly diagnosed high-grade glioma or diffuse intrinsic pontine glioma.</p> <p>Study details to be defined based on results of Study 3 and to be agreed with the PDCO before initiation of the study.</p>
Modelling and simulation analyses	<p>Study 5</p> <p>Physiologically-based pharmacokinetic modelling to determine the dose of AZD1390 to be used in the paediatric population from birth to less than 18 years of age.</p>
Other studies	Not applicable
Extrapolation plan	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2032
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:

The product is not authorised anywhere in the European Community.