MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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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-102524-PIP01-26

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

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 UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 19/06/2026 16:10 BST an application for a

The procedure started on 01/07/2026 07:49 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-102524-PIP01-26

Of 01/10/2026 11:44 BST

On the adopted decision for AZD1390; 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 (MHRA-102524-PIP01-26) 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 for AZD1390; 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, Film-coated tablet Age-appropriate oral dosage form , ORAL USE, OTHER .

This decision is addressed to AstraZeneca UK Limited, 2 Pancras Square, 8th floor , London, UNITED KINGDOM, N1C 4AG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of malignant neoplasms of the central nervous system The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age; Pharmaceutical form(s): Film-coated tablet Age-appropriate oral dosage form Route(s) of administration: Oral use Gastric use Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of malignant neoplasms of the central nervous system

2.2 Indication(s) targeted by the PIP:

Treatment of paediatric patients from 1 year to less than 18 years of age with newly diagnosed high grade glioma or diffusive intrinsic pontine glioma.

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

The paediatric population from 1 year to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet Age-appropriate oral dosage form The studies are: 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 1 year of age. 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 1 year to less than 18 years of age with newly diagnosed high-grade glioma or diffusive intrinsic pontine glioma (dose-finding part) and to determine the safety and antitumour activity of the recommended phase 2 dose of AZD1390 used in combination with radiotherapy (expansion part). Study 4 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 from1 year to less than 18 years of age with newly diagnosed high-grade glioma or diffusive intrinsic pontine glioma. Study details to be defined based on results of Study 3 and to be agreed with the Regulatory Agency before initiation of the study. Study 5 Physiologically-based pharmacokinetic modelling to determine the dose of AZD1390 to be used in the paediatric population from 1 year to less than 18 years of age. Concerns on potential long-term safety or 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

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	