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

MHRA-100232-PIP01-21

Scope of the Application

Active Substance(s)

ALECTINIB

Condition(s)

Treatment of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms)

Pharmaceutical Form(s)

Capsule, hard; Age appropriate oral liquid dosage form

Route(s) of Administration

Oral use

Name / Corporate name of the PIP applicant

Roche Products Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Roche Products Limited submitted to the licensing authority on 10/09/2021 15:02 BST an application for a Paediatric Investigation Plan

The procedure started on 04/02/2022 16:16 GMT

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

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-100232-PIP01-21

Of 17/02/2022 12:32 GMT

On the adopted decision for ALECTINIB (MHRA-100232-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 ALECTINIB, Capsule, hard; Age appropriate oral liquid dosage form , Oral use .

This decision is addressed to Roche Products Limited, 6 Falcon Way, Shire Park, , Welwyn Garden City, United Kingdom, AL7 1TW

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms)

2.2 Indication(s) targeted by the PIP:

Treatment of paediatric patients with anaplastic lymphoma kinase (ALK) fusion-positive solid or CNS tumour for whom prior treatment has proven to be ineffective, or for whom there is no satisfactory treatment available

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

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

2.4 Pharmaceutical Form(s):

Age appropriate oral liquid dosage form; Capsule, hard

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age appropriate oral formulation
Non-Clinical Studies	0	Not applicable
Clinical Studies	1	Study 2 Open label, single arm, three part trial to evaluate the recommended Phase 2 dose (RP2D) pharmacokinetics, pharmacodynamics (Part 1), activity and safety of alectinib (as Part 2- initial expansion and Part 3- additional expansion) in children from birth to less than 18 years of age with anaplastic lymphoma kinase (ALK) fusion-positive solid or CNS tumour for whom prior treatment has proven to be ineffective, or for whom there is no satisfactory treatment available.
Extrapolation, Modeling & Simulation Studies	1	Study 3 Modelling and simulation study to evaluate the use of alectinib in the proposed paediatric indication in children from birth to less than 18 years of age with anaplastic lymphoma kinase (ALK) fusion-positive solid or CNS tumour for whom prior treatment has proven to be ineffective, or for whom there is no satisfactory treatment available
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:	Yes
Date of completion of the paediatric investigation plan:	31/12/2027

Deferral of one or more studies contained in the paediatric investigation plan:	Yes