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

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

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

MHRA-100398-PIP01-21

# Scope of the Application

## Active Substance(s)

ralmitaront

## Condition(s)

Treatment of schizophrenia

## Pharmaceutical Form(s)

Film-coated tablet

## 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 21/01/2022 18:31 GMT an application for a Paediatric Investigation Plan

The procedure started on 23/08/2022 13:38 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-100398-PIP01-21

Of 03/10/2022 14:48 BST

On the adopted decision for ralmitaront (MHRA-100398-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 ralmitaront, Film-coated tablet , Oral use .

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

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Treatment of schizophrenia The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 13 years of age Pharmaceutical form(s): Film-coated tablet Route(s) of administration: Oral use Reason for granting waiver: 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(s):

| |
|---|
| Treatment of schizophrenia |

### 2.2 Indication(s) targeted by the PIP:

| |
|---|
| Treatment of schizophrenia |

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

| |
|---|
| The paediatric population from 13 years to less than 18 years of age |

### 2.4 Pharmaceutical Form(s):

| |
|---|
| Film-coated tablet |

### 2.5 Studies:

| Study Type | Number of Studies | Study Description |
|---|---|---|
| **Quality Measures** | 1 | Study 1 Development of a film coated tablet strength appropriate for dosing in adolescents. |
| **Non-Clinical Studies** | 1 | Study 2 Definitive juvenile toxicity study (20215458) in Wistar rats to support clinical evaluation of ralmitaront in children from 13 years to less than 18 years of age. |
| **Clinical Studies** | 2 | Study 3 Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of ralmitaront in children from 13 years to less than 18 years of age with schizophrenia. Study 4 Open label, non-comparative extension study to evaluate the long-term safety of ralmitaront in adolescents from 13 years to less than 18 years of age with schizophrenia. |
| **Extrapolation, Modeling & Simulation Studies** | 2 | Study 5 Physiologically based pharmacokinetic (PBPK) modelling and simulation study to evaluate the use of ralmitaront in the treatment of schizophrenia in children from 13 years to less than 18 years of age. Study 6 Modelling and simulation study to evaluate population pharmacokinetic (popPK) of ralmitaront in adolescent patients (and adults) with schizophrenia. |
| **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:** | 30/11/2031 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | Yes |