**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-101199-PIP01-23

# Scope of the Application

## Active Substance(s)

Inhibitor of receptor-interacting protein kinase 1

## Condition(s)

Treatment of ulcerative colitis

## Pharmaceutical Form(s)

Capsule, hard; Age appropriate oral dosage form

## Route(s) of Administration

ORAL USE

## Name / Corporate name of the PIP applicant

AbbVie Ltd

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AbbVie Ltd submitted to the licensing authority on 30/11/2023 13:07 GMT an application for a Paediatric Investigation Plan

The procedure started on 10/09/2024 15:13 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-101199-PIP01-23

Of 08/10/2024 08:29 BST

On the adopted decision for Inhibitor of receptor-interacting protein kinase 1 (MHRA-101199-PIP01-23) 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 Inhibitor of receptor-interacting protein kinase 1, Capsule, hard; Age appropriate oral dosage form , ORAL USE .

This decision is addressed to AbbVie Ltd, AbbVie House, Vanwall Road, Maidenhead, UNITED KINGDOM, SL6 4UB

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Treatment of ulcerative colitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Capsule, hard Age appropriate oral dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments. |

### 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

| |
|---|
| Treatment of ulcerative colitis |

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

| |
|---|
| Treatment of paediatric patients with moderately to severely active ulcerative colitis |

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

| |
|---|
| The paediatric population from 2 years to less than 18 years of age. |

## 2.4 Pharmaceutical Form(s):

| |
|---|
| Capsule, hard Age appropriate dosage form |

## 2.5 Studies:

| Study Type | Number of Studies | Study Description |
|---|---|---|
| **Quality Measures** | 1 | Study 1 Development of an age-appropriate oral formulation for paediatric use. |
| **Non-Clinical Studies** | 2 | Study 2 Dose range-finding juvenile toxicity study in rats. Study 3 Definitive juvenile toxicity study in rats. |
| **Clinical Studies** | 2 | Study 4 Open label 8- week induction followed by double-blind 44-week maintenance study in paediatric patients aged from 2 years to less than 18 years of age with ulcerative colitis (UC) to evaluate the efficacy, safety, and pharmacokinetics (PK) of ABBV-668. Study 5 Double-blind, placebo-controlled study to evaluate efficacy and safety of ABBV-668 in adolescents from 16 years to less than 18 years of age (and adults) with ulcerative colitis (UC). |
| **Extrapolation, Modeling & Simulation Studies** | 1 | Study 6 Modelling and simulation dose finding study to support use in children from 2 years to less than 18 years of age with ulcerative colitis (UC). |
| **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:** | 29/02/2040 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | Yes |