

Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decisionⁱ

Actives substances(s): Inhibitor of receptor-interacting protein kinase 1 (ABBV-668)

Latest Decision number(s): 1) P/0402/2023

Corresponding PIP number(s): 1) EMEA-003356-PIP01-22

If the PIP has been submitted as part of a marketing authorisation application in order to comply with the requirements of Article 7 of the Paediatric Regulation (as a condition of the validation of the respective application) and a marketing authorisation was granted based on this application, then there is a legal obligation to complete that PIP. The same applies if there has been a successful post-authorisation application, where the PIP was included in order to comply with the requirements of Article 8 of the Paediatric Regulation.

Please confirm if any of the above applies:

Yes ☐ No ☒

If yes, it means that based on the Marketing Authorisation obtained at the end of that initial procedure or the successful post-authorisation application, as applicable, you are obliged to complete that PIP. That obligation cannot be cancelled by a unilateral decision, including by withdrawing the MA. Such PIP must be completed, unless it is modified in agreement with the PDCO by removing all outstanding PIP measures or granting a full product-specific waiver instead (upon relevant circumstances in accordance with the Paediatric Regulation). Non-completion of a binding PIP establishes noncompliance with the requirements of the Paediatric Regulation, which the European Medicines Agency has an obligation to report to the European Commission.

Please note that development of the medicinal product above in the following **condition(s)/indication(s)**:

Treatment of ulcerative colitis

☒ has been discontinued

for the following reason(s): (tick all that apply)

☒ (possible) lack of efficacy in adults

☐ (possible) lack of efficacy in children

☐ (possible) unsatisfactory safety profile in adults

☐ (possible) unsatisfactory safety profile in children

☐ commercial reasons (please specify:)

☐ manufacturing / quality problems

☐ other regulatory action (please specify:)

☐ other reason (please specify:)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation:

AbbVie made the decision to discontinue development of ABBV-668. ABBV-668 was being developed for Ulcerative colitis (UC).

AbbVie voluntarily terminated all clinical development for ABBV-668. Based on the lack of efficacy in Study M21-446, a Phase 2a study in subjects with moderate to severe UC, a favourable benefit-risk profile was not established to support continued development of ABBV-668 monotherapy in UC, and therefore, the ABBV-668 clinical development program has been discontinued. The program was not discontinued due to safety reasons and there are no potential risks to the health of clinical trial subjects or other persons to disclose. Please note there are no ongoing clinical studies for ABBV-668 at this time.

Name and signature of the PIP contact point:

Date: 06.03.2026

Contact for inquiries from interested parties:

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Email: paediatricteam@abbvie.com

ⁱ This form will be published to the corresponding decision available on the website of the European Medicines Agency.