Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision[i]

Actives substances(s): Copanlisib (dihydrochloride)

Latest Decision number(s): 1) P/0385/2022

Corresponding PIP number(s): 1) EMEA-001757-PIP02-15-M03

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)**:

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

Treatment of mature B-cell neoplasms (full waiver)

Indication: Treatment of children with a relapsed or refractory neuroblastoma, Ewing sarcoma, osteosarcoma or rhabdomyosarcoma including at first relapse, in combination with chemotherapy.

☒ 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:

Copanlisib (approved under the brand name Aliqopa) was granted accelerated approval by the US FDA (Food and Drug Administration) in September 2017 for the treatment of adult patients with relapsed follicular lymphoma who have received at least two prior systemic therapies. The basis of approval was CHRONOS-1, an open-label, single-arm Phase II study. The US FDA required clinical benefit to be confirmed through the CHRONOS-4 study.

The CHRONOS-4 study did not meet the primary endpoint. The addition of copanlisib to standard immunochemotherapy did not improve progression-free survival, compared to the control arm of standard immunochemotherapy, in patients with relapsed iNHL, including FL. Based on the results, Bayer made the decision to stop the continued development of the copanlisib program.

Name and signature of the PIP contact point:	Signature on file
Date:	26/01/2024

Contact for inquiries from interested parties:

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