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

Actives substances(s): vibostolimab / pembrolizumab

Latest Decision number(s): 1) P/0424/2023

Corresponding PIP number(s): 1) EMEA-003063-PIP03-22

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 melanoma

☒ 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:

At a pre-planned analysis of Phase 3 study MK-7684A-010 (KEYVIBE-010) of adjuvant treatment of pembrolizumab with vibostolimab (MK-7684A) versus pembrolizumab in participants with high-risk stage II-IV melanoma, data showed that the primary endpoint of recurrence-free survival (RFS) met the pre-specified futility criteria. MK-7684A did not demonstrate a benefit in RFS, the study's primary endpoint, when compared to pembrolizumab monotherapy and the study met futility criteria at this pre-planned analysis. This outcome does not support further development of adjuvant MK-7684A in adults and paediatric patients with melanoma. Consequently, the plans of a Marketing Authorisation Application for the adjuvant treatment of adult patients with melanoma as well as the paediatric development in this condition are being discontinued.

Date: 14 June 2024

[i] This form will be published alongside the corresponding decision on the European Medicines Agency's website. Please ensure that this form does not contain any commercially confidential information and that the contact details for public enquiries are accurate on the website.