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

Actives substances(s): Cobolimab

Latest Decision number(s): 1) EMA/PE/0000246904

Corresponding PIP number(s): 1) EMA/PE/0000246904

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 all conditions included in the category of malignant neoplasms including lymphoma (except lung cancers and hematopoietic malignancies)

☒ 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:

The pivotal COSTAR Lung study completed all data collection required to support the planned analyses and all event number and quality targets were met. Neither combination regimen met the prespecified statistical threshold for the primary endpoint of superiority for overall survival for the Intent-to-Treat population of all comers. Consequently, GSK will not be filing for registration, will not be initiating any further studies, and will close out the cobolimab development program. The companion pediatric POPSTAR study also stopped enrollment and will initiate close out procedures.

GSK has made a decision to discontinue further development of Cobolimab for this study. The decision was made following the final analysis headline results from the COSTAR Lung study. GSK has shared these results with health authorities, and in addition plans to publish the findings in a manuscript. Based on these results the intended future cohorts in POPSTAR study will not open for enrolment and the study will be terminated once the safety monitoring for cohorts 1a and 1b participants is complete.

Date: 15 October 2025

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.