

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

Actives substances(s): Nemvaleukin alfa

Latest Decision number(s): EMA/PE/0000231113

Corresponding PIP number(s): EMA/PE/0000231113

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 (except central nervous system, haematopoietic and lymphoid tissue)
- Treatment of malignant neoplasms of the lymphoid tissue

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:

Following review of data from the phase 3 ARTISTRY-7 trial and the phase 2 ARTISTRY-6 trial, Mural will discontinue all clinical development of nemvaleukin.

ARTISTRY-7 is a phase 3 trial comparing nemvaleukin in combination with pembrolizumab vs. investigator choice single agent chemotherapy in patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, with a primary endpoint of overall survival. In the pre-specified interim analysis conducted by the independent data monitoring committee, nemvaleukin in combination with pembrolizumab did not achieve a statistically significant improvement in overall survival versus investigator's choice chemotherapy alone and the company believes the study is highly unlikely to achieve success at the final analysis. Median overall survival was 10.1 months for patients treated with nemvaleukin in combination with pembrolizumab and 9.8 months for patients treated with investigator's choice chemotherapy (hazard ratio: 0.98)

ARTISTRY-6, cohort 2 is a phase 2, single-arm trial evaluating nemvaleukin as a monotherapy in 92 patients with mucosal melanoma with a minimum follow-up of at least six months. A review of the topline data from this cohort showed that the primary endpoint was not achieved. Mural also conducted a review of preliminary data from ARTISTRY-6, cohort 3, evaluating less-frequent intravenous dosing of nemvaleukin in patients with cutaneous melanoma, and did not observe a level of activity that warranted continuation.

Based on the totality of these data, together with the interim overall survival results from ARTISTRY-7, Mural will discontinue all clinical development of nemvaleukin.

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