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

Actives substances(s): Iodine (131-I) murine IgG1 monoclonal antibody against B7-H3 (^{131}I-omburtamab)

Latest Decision number(s): 1) P/0322/2020

Corresponding PIP number(s): 1) EMEA-002101-PIP02-18-M01

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 neuroblastoma

☒ 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: corporate business decision)

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

Trial 101 was terminated earlier. An end of trial notification was submitted to the Agency in Denmark, Spain and the UK on 16 June 2023.

The closure was a corporate business decision and not due to safety or efficacy concerns. The last treatment in the trial was administered 19-Jan-2023. A total of 52 patients were enrolled. All patients had completed the minimum safety follow-up of 3 weeks after last IMP administration (as stated in section 10.8 of the protocol). As of 30-May-2023, all reported SAEs and AESIs had been recovered.

The trial was terminated earlier because there was no rationale to continue development of 131I-omburtamab for this patient population. In December 2022, the CHMP recommended the refusal of the marketing authorisation for 131I-omburtamab because they considered that it was not possible to conclude on the effectiveness of the product.

Date: 20 January 2026

Contact for inquiries from interested parties:

Telephone: +45 7026 1414

Email: info@ymabs.com

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