To:

Head of Paediatric Medicines
European Medicines Agency

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

Actives substances(s): Depatuxizumab mafodotin

Invented name: Andeltic / Aladcia

Latest Decision number(s): 1) P/0298/2016 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001732-PIP02-15 2) EMEA- 3) EMEA- 4) EMEA-

Date of initial marketing authorisation granted: N/A

Date of authorisation of new indication, pharmaceutical form or route of administration: N/A

Please note that development of the medicinal product above in the following **condition(s)/indication(s)**:

Treatment of high-grade glioma

☒ has been discontinued

☐ has been suspended/put on long-term hold (with possible re-start at a later time)

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:) (e.g. suspension, revocation of M.A.)

☐ other reason (please specify:)

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

The Independent Data Monitoring Committee (IDMC) for the study INTELLANCE-1 (M13-813), in newly diagnosed glioblastoma, convened to review the results of the protocol-specified interim efficacy analysis on 13 May 2019. The IDMC recommended that the trial be stopped due to futility as no survival benefit was observed for depatuxizumab mafodotin (ABT-414) compared with placebo when added to the standard first-line regimen of temozolomide and radiation; no new safety findings were

noted. AbbVie has accepted this recommendation and has decided to stop the development of depatuxizumab mafodotin in glioblastoma.

Please note that 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 to the PIP in question:

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.

Name and signature of the PIP contact point:	Signature on file
Date:	05 July 2019

Contact for inquiries from interested parties:	Ruth Flynn
Telephone:	+44 (0) 7887764740
Email:	ruth.flynn@abbvie.com