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): Ibrutinib

Invented name: Imbruvica

Latest Decision number(s): 1) P/0021/2019 2) P/0421/2019
3) P/0295/2023

Corresponding PIP number(s): 1) EMEA-001397-PIP04-17 2) EMEA-001397-PIP04-17-M01
3) EMEA-001397-PIP04-17-M02

Date of initial marketing authorisation granted: 21 October 2014

Date of authorisation of new indication, pharmaceutical form or route of administration: N/A for chronic graft-versus-host disease (cGvHD) indication

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

Treatment of chronic graft-versus-host disease (cGvHD)

☒ 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: see below)

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

The Phase 3 Study PCYC-1140-IM in subjects with New Onset Chronic Graft Versus Host Disease (cGVHD) did not meet it's primary endpoint. As a result, the Applicant does not intend to pursue the adult cGVHD indication in the EU. The potential paediatric cGVHD indication in the EU was intended to

be based on extrapolation of the efficacy results in adult patients from study PCYC-1140 and the Phase 1/2 paediatric study PCYC-1146.

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:	11 October 2023

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