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): momelotinib

Invented name: N/A

Latest Decision number(s): 1) P/0157/2015

Corresponding PIP number(s): 1) EMEA-001656-PIP01-14

Date of initial marketing authorisation granted: Not yet authorised

Date of authorisation of new indication, pharmaceutical form or route of administration: Not yet authorised

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

Treatment of acute lymphoblastic leukaemia

☒ 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 applicant considers it unlikely that momelotinib can provide a significant therapeutic benefit over existing treatments for paediatric and adult patients with ALL due to the following factors:

- A potential role for JAK inhibition has only been described in Ph-like ALL subset (Bohm at al, 2021), but there is no compelling clinical evidence of efficacy for a JAK inhibitor in this population to date.

- The most common site of extramedullary involvement in ALL is the central nervous system, and MMB does not cross the blood-brain barrier.

- The therapeutic landscape in ALL has evolved since the paediatric development plan was proposed by the previous sponsor of momelotinib (Gilead) in 2015. In the context of the new treatment options available to these patients, including blinatumomab and CAR-T cell therapies, JAK inhibition is expected to be of limited clinical utility (Kunz et al, 2022).

References provided upon request.

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:	13 November 2023

Contact for inquiries from interested parties:	GlaxoSmithKline Trading Services Limited
Telephone:	+1 438-899-8201
Email:	eu.paediatric-plans@gsk.com