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): Empagliflozin

Invented name: Jardiance

Latest Decision number(s): 1) P/0345/2019

Corresponding PIP number(s): 1) EMEA-000828-PIP04-16-M03

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 type 1 diabetes mellitus

☒ 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 brief description below)

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

Boehringer Ingelheim in collaboration with Eli Lilly and Company completed a global phase 3 clinical development program in 2018 which evaluated the efficacy and safety of empagliflozin 2.5 mg, 10 mg, and 25 mg as adjunct to insulin therapy for adults with type 1 diabetes (T1D).

In May 2019, Boehringer Ingelheim submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) with the intent to register a 2.5mg empagliflozin dose as adjunct to insulin therapy in adults with T1D under a separate trade name.

On 13 Nov 2019, the FDA convened an Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) which voted 14:2 against the approval of empagliflozin 2.5mg dose as an adjunct to insulin therapy for adults with T1D. On 20 Mar 2020, FDA issued a complete response letter (CRL) to Boehringer Ingelheim in regard to this sNDA stating that the agency is unable to approve the application in its current form. This outcome was consistent with the EMDAC recommendations.

At this stage, Boehringer Ingelheim does not plan to further pursue the registration of empagliflozin 2.5mg as adjunct to insulin therapy in adults with T1D in the US or any other country including the EU.

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:	27 September 2021

Contact for inquiries from interested parties:	Boehringer Ingelheim International GmbH
Telephone:	0049 6132 77 8271
Email:	COMMSPaediatrics@boehringer-ingelheim.com