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): Tofacitinib

Invented name: N/A

Latest Decision number(s): 1) P/0055/2017

Corresponding PIP number(s): 1) EMEA-000576-PIP02-11-M04

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 psoriasis

Treatment of severe plaque psoriasis from 6 to less than 18 years of age

☒ 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: Pfizer business decision to not pursue PsO indication in adults, based on FDA complete response letter)

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

Applications for the PsO indication were submitted in the US (11th December 2014) and in other countries (although not the EU) with a proposed indication for the treatment of adult patients with moderate to severe chronic plaque PsO who are candidates for systemic therapy or phototherapy. On October 2015, the Food Drug and Administration (FDA) Division of Dermatology and Dental Products provided Pfizer a complete response letter noting that the submitted data did not support marketing of tofacitinib for moderate to severe chronic plaque psoriasis (PSO). The FDA's view was that the benefits did not outweigh the risks for the indication of moderate to severe plaque psoriasis and provided additional recommendations (potentially identifying a patient subpopulation with a more favourable benefit risk and providing additional safety data on events of special interest such as cardiovascular, opportunistic infections and malignancy) to support a resubmission.

Based on an internal assessment, Pfizer made the determination that there was insufficient evidence to satisfactorily address FDA's comments and, subsequently submitted a request to withdraw the supplementary New Drug Application (sNDA) in July 2016, without prejudice to refiling. Similarly, all pending global applications were withdrawn in July 2016. Note that tofacitinib 5 mg BID and 10 mg BID is approved for the treatment of plaque PsO in Russia.

Given the above, it is considered appropriate to discontinue the PsO PIP in 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: 04/05/2023

Contact for inquiries from interested parties:

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