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): dupilumab

Invented name: Dupixent

Latest Decision number(s): 1) P/0120/2022

Corresponding PIP number(s): 1) EMEA-001501-PIP09-21

Date of initial marketing authorisation granted: 2017-09-26

Date of authorisation of new indication, pharmaceutical form or route of administration:
06 June 2019: EMEA/H/C/004390/II/0004/G - Addition of a new strength 200 mg and a new indication for Asthma

01 Aug. 2019: EMEA/H/C/004390/II/0012 - Addition of a new indication for adolescents with Atopic Dermatitis

24 Oct. 2019: EMEA/H/C/004390/II/0017 - Addition of a new indication: Chronic Rhinosinusitis with nasal polyposis in adults

25 June 2020: EMEA/H/C/004390/II/0018/G - Addition of a new pharmaceutical presentation for the 300 mg dose: A prefilled pen

25 Nov. 2020: EMEA/H/C/004390/II/0027 - Addition of a new indication for children 6 to 11 years with Atopic Dermatitis

04 April 2022: EMEA/H/C/004390/II/0045 - Addition of a new indication for pediatric 6-11 years with Asthma

29 sept. 2022: EMEA/H/C/004390/II/0059/G - Addition of a new prefilled pen derived from Autoinjector sub-assemblies variant

12 Dec. 2022: EMEA/H/C/004390/II/0063 - Addition of a new indication: Prurigo Nodularus in adults

23 Jan. 2023: EMEA/H/C/004390/II/0062 - Addition of a new indication: Eosinophilic esophagitis in adults and adolescents

15 March 2023: EMEA/H/C/004390/II/006à - Addition of a new indication for infant from 6mo-5yo with Atopic Dermatitis

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

Treatment of chronic inducible cold urticaria

☒ 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 phase 3 study EFC16720 investigating dupilumab for the treatment of cold inducible chronic urticaria (ColdU) in adults and adolescents, referred to as study 1 in EMEA-001501-PIP09-21, did not meet the pre-specified efficacy endpoint at primary analysis. The primary analysis of Study EFC16720 did not support pursuing clinical development in this indication.

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: 26 January 2024

Contact for inquiries from interested parties:

Telephone:

Email: contact-us@sanofi.com