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): Secukinumab

Invented name: Cosentyx

Latest Decision number(s): 1) P/0423/2022

Corresponding PIP number(s): 1) EMEA-000380-PIP06-19-M01

Date of initial marketing authorisation granted: 15/01/2015

Date of authorisation of new indication, pharmaceutical form or route of administration: Since the submission of the preceding procedure (EMEA-000380-PIP06-19-M01), the marketing authorisation has changed:

1. An extension of indication to include the treatment of Juvenile Idiopathic Arthritis (Enthesitis-Related Arthritis and Juvenile Psoriatic Arthritis) in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy for Cosentyx alone or in combination with methotrexate (II/0079) was approved on 20 June 2022.

2. An extension of indication to include the treatment of active moderate to severe Hidradenitis Suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy (II/0090) was approved on 26 May 2023.

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

Treatment of systemic lupus erythematosus

☒ 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:

On 26 May 2023, Novartis has decided to terminate the clinical study CAIN457Q12301 (the "Core Study") and the related extension study, CAIN457Q12301E1 (the "Extension Study"), in lupus nephritis patients, effective immediately.

The results of an intermediate analysis showed that no clinically meaningful benefit of secukinumab above the current standard of care is expected to be observed by the end of the Core study. No new safety signals were observed.

Novartis has informed the relevant Health Authorities of its decision.

The related agreed paediatric investigation plan of secukinumab in the condition of Systemic Lupus Erythematosus, (EMA-000380-PIP06-19-M01, including all the measures from study 1 to study 3), is therefore discontinued.

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: 18/07/2023

Contact for inquiries from interested parties: paediatric.enquiries@novartis.com

Telephone: +41 61 324 1111

Email: paediatric.enquiries@novartis.com