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): benralizumab

Invented name: Fasenra

Latest Decision number(s): 1) P/0388/2021

Corresponding PIP number(s): 1) EMEA-001214-PIP05-19

Date of initial marketing authorisation granted: 18 January 2018

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)**:

Eosinophilic esophagitis

☒ 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:

High-level results from the MESSINA Phase III trial showed that AstraZeneca's Fasenra (benralizumab) did not meet one of the two dual-primary endpoints. Fasenra demonstrated a

statistically significant improvement in histological disease remission, but not a change in dysphagia symptoms, compared to placebo, in patients with EoE aged 12 years or older.

In the trial, histological disease remission was measured as the proportion of patients with less than or equal to six eosinophils per high power field at Week 24. Burden of dysphagia was assessed using the patient-reported Dysphagia Symptom Questionnaire (DSQ) and measured as a mean change from baseline at Week 24. The trial included 210 patients, who received either Fasenra or placebo at four-week intervals.

The safety and tolerability profile for Fasenra in the trial was consistent with the known profile of the medicine.

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:	14 November 2022
Contact for inquiries from interested parties:	AstraZeneca
Telephone:	+46 8 553 244 00
Email:	paediatrics@astrazeneca.com