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): fluticasone furoate, vilanterol trifenatate and umeclidinium bromide

Invented name: Trelegy Ellipta

Latest Decision number(s): 1) P/0058/2020

Corresponding PIP number(s): 1) EMEA-002153-PIP01-17-M01

Date of initial marketing authorisation granted: 15/11/2017

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)**:

Maintenance treatment of asthma in patients aged 5 years or older who have inadequately controlled asthma despite therapy with inhaled corticosteroids and long acting beta agonists.

☒ 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: Negative CHMP Opinion received on 25th February 2021 to add an asthma indication in adults) (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 27th January 2020, GSK submitted a Type II variation (Line Extension) application to include asthma as an additional indication in adults at a dose of 100/62.5/25 mcg and 200/62.5/25 mcg

inhalation powder once daily in the Trelegy Ellipta label. On 25th February 2021, the EMA adopted a negative opinion for the Trelegy Ellipta application in the EU.

The EMA considered that an improvement in lung function alone is not enough to show that a medicine is suitable for treating asthma and that the main study did not clearly show that the medicine was effective at reducing asthma attacks or controlling symptoms.

Therefore, the EMA's opinion was that the benefits of Trelegy Ellipta in the treatment of asthma did not outweigh its risks. Hence, the EMA recommended refusing the change to the marketing authorisation.

As per the strategy agreed in the paediatric investigation plan (PIP), PIP number P/0076/2018, paediatric development of FF/UMEC/VI inhalation powder was to commence following a positive outcome in the Phase 3 registration study in adults (GSK Study 205715). Paediatric studies would progress in a sequential manner based on age, initially in adolescents 12-17 years and subsequently in children 5-11 years. However, following the recent negative opinion to register asthma in adults, GSK would like to notify the EMA of its plans to discontinue paediatric development in asthma.

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: 23rd April 2021

Contact for inquiries from interested parties: eu.paediatric-plans@gsk.com

Telephone: +44 208 047 7604

Email: eu.paediatric-plans@gsk.com