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): Molnupiravir

Invented name: N/A

Latest Decision number(s): 1) P/0553/2021

Corresponding PIP number(s): 1) EMEA-002940-PIP02-21

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)**:

Prevention of coronavirus disease 2019 (COVID-19)

☒ 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 paediatric clinical program for COVID-19 prevention consisted of a full extrapolation of efficacy from the adult COVID-19 prevention trial (MK-4482-013, MOVe-AHEAD) to the paediatric population using a population PK model. Topline results from study MK-4482-013 evaluating molnupiravir for the prevention of COVID-19 (laboratory-confirmed SARS-CoV-2 infection with symptoms) in adults residing with a person with COVID-19 were shared with the Agency on 21 February 2023: Molnupiravir did not

demonstrate a statistically significant reduction in the risk of COVID-19 infection following household exposure to another individual with COVID-19.In the primary efficacy analysis population who did not have evidence of SARS-CoV-2 infection at baseline (confirmed by a negative SARS-CoV-2 test), the molnupiravir treated group was observed to be 23.6% less likely than those who received placebo to develop COVID-19 through Day 14 (a positive post-baseline SARS-CoV-2 test with evidence of signs and symptoms). As this difference was not statistically significant, the primary endpoint was not met. Consequently, the extrapolation study and paediatric development for prevention of COVID-19 could not be conducted.

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: 31 March 2023

Contact for inquiries from interested parties: Merck Sharp & Dohme (Europe) Inc.

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