Public

Merck Sharp & Dohme (Europe), Inc.
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c/o : PO Box 20, 5340 BH Oss, The Netherlands

[redacted]

MSD

To: Chair of the CHMP, Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam (The Netherlands)

21 June 2023

Subject: Withdrawal of Marketing Authorization Application for LAGEVRIO, molnupiravir, 200 mg hard capsules, EMEA/H/C/005789

Dear Dr Enzmann,

I would like to inform you that, at this point of time, Merck Sharp & Dohme B.V. has taken the decision to withdraw the application for Marketing Authorization of LAGEVRIO (molnupiravir), 200 mg hard capsules, which was intended to be used for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.

This withdrawal is based on the following reason: MSD has taken this decision based on the CHMP's view that the data provided do not allow the committee to conclude on a positive benefit-risk balance for LAGEVRIO at this time.

MSD respectfully disagrees with the CHMP's assessment, and considers that the totality of the scientific evidence, including the positive results from the Phase 3 placebo-controlled trial studying LAGEVRIO for the treatment of non-hospitalized patients with mild-to-moderate COVID-19 who are at high risk for progression to severe COVID-19, supports a positive benefit-risk assessment for LAGEVRIO for the treatment of adults with COVID-19.

We would like to take this opportunity to thank the (Co-)Rapporteurs, CHMP and EMA for their time reviewing this application.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website in a redacted manner.

Yours sincerely,

[redacted]