Merck Sharp & Dohme (Europe) Inc.
Siège d'exploitation: Boulevard du Souverain 25, 1170 Bruxelles
Exploitatiezetel: Vorstlaan 25, 1170 Brussel
[redacted]

[redacted]

MSD

Brussels, July 14, 2023

Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of the initial Marketing Authorisation Application for GEFZURIS, gefapixant, 45mg, film-coated tablet - **EMEA/H/0005884**

Dear Dr. Enzmann,

We would like to inform you that, at this point of time, Merck Sharp & Dohme B.V. has taken the decision to withdraw the above mentioned application for the **duplicate** Marketing Authorisation of gefapixant, 45mg, film-coated tablet, which was intended to be used for the treatment of refractory or unexplained chronic cough in adults.

This withdrawal is based on a change to the applicant's strategy for the duplicate MAA. This is unrelated to product's quality or safety.

Registration clinical trials for gefapixant have been completed.

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.

[redacted]