ApoPharma

10 August 2020

Dr. Harald Enzmann
CHMP Chair
European Medicines Agency (EMA)
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: UPKANZ (deferiprone) 80 mg/mL oral solution - EMEA/H/C/005004
Withdrawal of Initial Marketing Authorisation Application

Dear Dr. Enzmann,

ApoPharma, on behalf of Apotex B.V., is hereby withdrawing the Marketing Authorisation Application (MAA) for UPKANZ (deferiprone) 80 mg/mL oral solution, submitted for the following proposed therapeutic indication: Treatment of pantothenate kinase associated neurodegeneration (PKAN) in patients aged 4 years and older.

The withdrawal is a consequence of the reassessment of regulatory and business strategies associated with the development and marketing of UPKANZ (deferiprone) in the European Union by the Chiesi Group, headquartered at Via Palermo 26/A, Parma, Italy. Chiesi Farmaceutici S.p.A. acquired the rights to the product on 08 January 2020. The withdrawal is without prejudice to resubmission.

There are no ApoPharma-sponsored clinical trials or compassionate use programs on pantothenate kinase associated neurodegeneration that are ongoing in the European Union.

We will continue to notify the EMA in accordance with established guidelines prior to the submission of future Marketing Authorisation Applications.

I agree with the publication of this letter on the EMA website.

Should you have any questions regarding this letter, please do not hesitate to contact the undersigned by e-mail

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