

Harald Enzmann
Mr. Chair of CHMP
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

S. Mamede do Coronado, 12th March 2024

Subject: Withdrawal of the request for extension of indication

Dear Dr Harald Enzmann,

Pursuant to Article 16 of Commission Regulation (EC) No 1234/2008, Bial - Portela & C^a, S.A. (hereinafter BIAL) submitted to the European Medicines Agency on 25 July 2023 an application for a variation following a worksharing procedure (WS) according to Article 20 of Commission Regulation (EC) No 1234/2008 - *Extension of indication to include treatment of signs and symptoms of Parkinson's Disease*.

We would like to inform you that, at this point in time, BIAL has taken the decision to withdraw the application to extend the use of opicapone in early stable Parkinson's disease stage.

This withdrawal is based on the need to conduct additional work to fully address the questions raised by the CHMP.

We remain fully committed to the development of opicapone to early idiopathic Parkinson's Disease patients and reserve the right to make further application for Ongentys/Ontilyv Marketing Authorisations.

Bial would like to sincerely thank the Rapporteur, the EMA and the CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

I agree for this letter to be published on the EMA website.

Yours sincerely,

BIAL-Portela & C^a, S.A.