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Att. Dr. Enzmann
European Medicines Agency (EMA)
Human Medicines Development and Evaluation
Domenico Scarlattilaan 61083 HS Amsterdam
The Netherlands

11 October 2022

Subject: **Withdrawal of Orepaxam (Treprostinil diolamine) 0.125 / 0.25 / 1 / 2.5 / 5 mg prolonged-release tablets - H0005990**

Dear Dr. Enzmann,

I would like to inform you that, at this point of time, Ferrer Internacional, S.A. has taken the decision to withdraw the application for Marketing Authorisation of Orepaxam (Treprostinil diolamine) 0.125 / 0.25 / 1 / 2.5 / 5 mg prolonged-release tablets (full witdrawal), which was intended to be used for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to delay disease progression and to improve exercise capacity.

This withdrawal is based on the fact that further clinical evidence may be highly requested, which could not be adequately addressed during the clock stop period of 6 months.

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

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

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

Yours sincerely

[redacted]

[redacted]