

30-October-2025

Professor Bruno Sepodes
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Ohtuvayre (ensifentrine), 3mg, Nebuliser Suspension -
EMA/H/C/006742/0000

Dear Professor Sepodes,

I would like to inform you that on October 7, 2025, Merck & Co., Inc. (Rahway, NJ USA) known as MSD outside of the United States and Canada ("MSD"), announced acquisition of Verona Pharma Ireland Limited ("Verona Pharma"). Verona Pharma is now a wholly owned subsidiary of MSD.

Given the acquisition, the applicant, Verona Pharma has taken the decision to withdraw the application for Marketing Authorisation of Ohtuvayre (ensifentrine), 3 mg nebulizer suspension, which was intended to be used for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

This withdrawal is based on recent internal strategic review of the product development and commercialization priorities between Verona Pharma and MSD. After careful consideration, we have concluded that continuing the MAA process for Ohtuvayre is not aligned with current business objectives and portfolio strategy.

The withdrawal has no consequences with respect to efficacy nor safety for ongoing trials assessing ensifentrine.

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

Verona Pharma would like to take this opportunity to sincerely thank the (Co-)Rapporteurs, PRAC, CHMP and EMA for their time dedicated and consideration for this application.

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

Yours sincerely,

