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Withdrawal of application for the marketing authorisation of Ohtuvayre (ensifentrine)

Verona Pharma Ireland Limited withdrew its application for a marketing authorisation of Ohtuvayre for the treatment of chronic obstructive pulmonary disease (COPD).

The company withdrew the application on 30 October 2025.

What is Ohtuvayre and what was it intended to be used for?

Ohtuvayre was developed as a medicine for maintenance treatment for adults with symptoms of chronic obstructive pulmonary disease (COPD), a long-term disease in which the airways and air sacs in the lungs become damaged or blocked, leading to difficulty breathing.

Ohtuvayre contains the active substance ensifentrine and was to be inhaled using a standard jet nebuliser.

How does Ohtuvayre work?

The active substance in Ohtuvayre, ensifentrine, blocks the actions of two enzymes (proteins) called phosphodiesterase type 3 and phosphodiesterase type 4. Type 3 is involved in contraction of the muscles in the airways of the lungs, while type 4 is involved in inflammation.

By blocking the actions of these enzymes, the medicine was expected to widen the airways and reduce inflammation in the lungs, making it easier to breathe.

What did the company present to support its application?

The company presented results from two main studies involving 1,553 people with moderate-to-severe COPD. The studies compared Ohtuvayre with placebo (a dummy treatment) and looked at the change in a measure of FEV_1 after 12 weeks of treatment. FEV_1, or forced expiratory volume in 1 second, is the most air a person can breathe out in 1 second.

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn while the European Medicines Agency was still evaluating the initial information from the company.

What did the Agency recommend at that time?

As the Agency was still evaluating the initial information from the company, it had not yet made any recommendations.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that it withdrew the application following a review of its priorities.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that the withdrawal will have no consequences for people in clinical trials using Ohtuvayre.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.