

## Ohtuvayre™ (ensifentrine) – New drug approval

- On June 26, 2024, [Verona Pharma announced](#) the FDA approval of [Ohtuvayre \(ensifentrine\)](#), for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.
- Approximately 8.6 million people in the U.S. are treated chronically for COPD.
- Ohtuvayre is a first-in-class selective dual inhibitor of the enzymes phosphodiesterase 3 and phosphodiesterase 4 (PDE3 and PDE4). Inhibition of both enzymes is believed to have a bronchodilator and non-steroidal anti-inflammatory effect.
- The efficacy of Ohtuvayre was established in two randomized, double-blind, placebo-controlled studies (ENHANCE-1 and ENHANCE-2) in a total of 1,553 adults with moderate to severe COPD. In both studies, patients received Ohtuvayre or placebo. The primary endpoint was average forced expiratory volume in the first second (FEV<sub>1</sub>) area under the curve (AUC)<sub>0–12 h</sub> post dose at 12 weeks.
  - In ENHANCE-1, the least squares (LS) mean change from baseline in FEV<sub>1</sub> AUC<sub>0–12h</sub> at week 12 was 61 mL with Ohtuvayre vs. -26 mL with placebo (difference 87, 95% CI: 55, 118; p < 0.0001).
  - In ENHANCE-2, the LS mean change from baseline in FEV<sub>1</sub> AUC<sub>0–12h</sub> at week 12 was 48 mL with Ohtuvayre vs. -46 mL with placebo (difference 94, 95% CI: 65, 124; p < 0.0001).
- Warnings and precautions for Ohtuvayre include acute episodes of bronchospasm, paradoxical bronchospasm, and psychiatric events including suicidality.
- The most common adverse reactions (≥ 1% and more common than placebo) with Ohtuvayre use were back pain, hypertension, urinary tract infection, and diarrhea.
- The recommended dosage of Ohtuvayre is 3 mg (one unit-dose ampule) twice daily, once in the morning and once in the evening, administered by oral inhalation using a standard jet nebulizer with a mouthpiece.
- Verona Pharma plans to launch Ohtuvayre in the third quarter 2024. Ohtuvayre will be available as a 3 mg/2.5 mL aqueous suspension in unit-dose ampules.