

Nuance Pharma Announces Approval of Ohtuvayre® (ensifentrine) in Hong Kong SAR, China

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Approval marks the second regulatory approval outside of the U.S. Food and Drug Administration, further expanding access to COPD patients in select Special Administrative Regions (SARs) in Greater China

SHANGHAI, March 12, 2026 /PRNewswire/ -- Today, Nuance Pharma ("Nuance") announced that the Hong Kong Drug Office approved Ohtuvayre® (ensifentrine) for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients under the "1+ mechanism."

Ohtuvayre® is the first novel inhaled mechanism for the treatment of COPD in more than 20 years and combines bronchodilator and non-steroidal anti-inflammatory effects. The U.S. Food and Drug Administration approved Ohtuvayre in June 2024 for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

The approval of Ohtuvayre in Hong Kong SAR, China, was based on the Global Phase 3 ENHANCE trials and referencing the completed ENHANCE-CHINA trial. In the ENHANCE trials, Ohtuvayre demonstrated clinical benefits both alone and when used in combination with a LABA, a LABA+ICS, a LAMA, or a LAMA+ICS.

Mark Lotter, founder and Chief Executive Officer of Nuance Pharma, said: "We are pleased to announce that the Hong Kong regulatory authority has approved the registration of Ohtuvayre under the "1+ mechanism," which also marks the second regulatory approval outside of the U.S. We are proud to provide access to this highly innovative COPD treatment to patients in Hong Kong and Macau."

Ohtuvayre was approved by the Pharmaceutical Administration Bureau Macau in February 2025, and was introduced in the Greater Bay Area in November 2025 through the "Hong Kong and Macau Medicine and Equipment Connect" policy and can be used in designated medical institutions. In November 2024, Nuance Pharma launched Ohtuvayre in China's Hainan Boao Pilot Zone through an early access program. In January 2026, Nuance Pharma announced acceptance for review of the new drug application for Ohtuvayre by the national medical products administration of China.

In 2021, Nuance Pharma entered into an agreement with Verona Pharma for the exclusive rights to develop and commercialize Ohtuvayre in Greater China (mainland China, Hong Kong, Macau and Taiwan).

In October 2025, Merck & Co., Inc., Rahway, N.J., USA, known as MSD outside the United States and Canada, announced the completion of the acquisition of Verona Pharma plc. MSD holds the exclusive rights to develop and commercialize Ohtuvayre in all markets outside of Greater China.

About Ohtuvayre® (ensifentrine)

Ohtuvayre® is the first inhaled therapy for the maintenance treatment of COPD in adult patients that combines bronchodilator and non-steroidal anti-inflammatory activities in one molecule. Ohtuvayre was evaluated in a Phase 3 clinical program ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") for COPD maintenance treatment. Ohtuvayre met the primary endpoint in both ENHANCE-1 and ENHANCE-2, demonstrating statistically significant and clinically meaningful improvements in lung function.

Ohtuvayre Indication and Important Safety Information

INDICATION

Ohtuvayre is indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

IMPORTANT SAFETY INFORMATION

Contraindication: Ohtuvayre is contraindicated in patients with hypersensitivity to ensifentrine or any component of this product.

Warnings and Precautions:

Acute Episodes of Bronchospasm Ohtuvayre should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled, short-acting bronchodilator.

Paradoxical Bronchospasm As with other inhaled medicines, Ohtuvayre may produce paradoxical bronchospasm, which may be life threatening. If paradoxical bronchospasm occurs following dosing with Ohtuvayre, it should be treated immediately with an inhaled, short-acting bronchodilator. Ohtuvayre should be discontinued immediately and alternative therapy should be instituted.

Psychiatric Events Including Suicidality Before initiating treatment with Ohtuvayre, healthcare providers should carefully weigh the risk and benefits of treatment with Ohtuvayre in patients with a history of depression and/or suicidal thoughts or behavior. Patients, their caregivers, and families should be advised of the need to be alert for the emergence or worsening of insomnia, anxiety, depression, suicidal thoughts, or other mood changes, and if such changes occur to contact their healthcare provider. Healthcare providers should carefully evaluate the risks and benefits of continuing treatment with Ohtuvayre if such events occur.

Treatment with Ohtuvayre is associated with an increase in psychiatric adverse reactions. Psychiatric events including suicide-related adverse reactions were reported in clinical studies in patients who received Ohtuvayre (1 suicide attempt and 1 suicide). Additionally, the most commonly reported psychiatric adverse reactions in the pooled 24-week safety population were insomnia (6 patients [0.6%] Ohtuvayre 3 mg; 2 patients [0.3%] placebo), and anxiety (2 patients [0.2%] Ohtuvayre 3 mg; 1 patient [0.2%] placebo). Depression-related reactions including depression, major depression, and adjustment disorder with depressed mood occurred in 4 patients [0.4%] receiving Ohtuvayre and no patients receiving placebo.

Adverse Reactions: The most common adverse reactions $\geq 1\%$ in Ohtuvayre and greater than placebo in the pooled population were back pain 1.8%, hypertension 1.7%, urinary tract infection 1.3%, and diarrhea 1.0%.

These are not all of the possible risks associated with Ohtuvayre.

Please see Prescribing Information for Ohtuvayre (ensifentrine) at:

<https://ohtuvayrehcp.com/wp-content/uploads/sites/2/2024/11/Ohtuvayre-US-Prescribing-Information.pdf>, **Patient Information for Ohtuvayre at:**

<https://ohtuvayre.com/wp-content/uploads/2024/11/Ohtuvayre-US-Prescribing-Information.pdf>.

About Nuance Pharma

Nuance Pharma is an innovation-focused biopharmaceutical company, with both late-stage clinical pipeline and commercial stage asset portfolio. Focusing on specialty care, Nuance has established a differentiated combination of commercialized assets and innovative pipeline across respiratory, pain management, emergency care and iron deficiency anemia. With the mission to address critical unmet medical needs in Asia Pacific, Nuance deploys the Dual Wheel model that develops a global leading innovative pipeline, while maintaining a self-sustainable commercial operation in both China and Asia as a region. For more information, please visit www.nuancepharma.com.

Forward-looking Statements

This news release may make statements that constitute forward-looking statements, including descriptions regarding the intent, belief or current expectations of the Company or its officers with respect to the business operations and financial condition of the Company, which can be identified by terminology such as "will," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," "confident" and similar statements. Such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, or other factors, some of which are beyond the control of the Company and are unforeseeable. Therefore, the actual results may differ from those in the forward-looking statements as a result of various factors and assumptions, such as future changes and developments in our business, competitive environment, political, economic, legal and social conditions. The Company or any of its affiliates, directors, officers, advisors or representatives has no obligation and does not undertake to revise forward-looking statements to reflect new information, future events or circumstances after the date of this news release, except as required by law.

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