

Trixeo Aerosphere receives positive CHMP opinion

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Trixeo Aerosphere recommended for approval in the EU by CHMP for the maintenance treatment of COPD

Recommendation of triple-combination therapy based on positive results from ETHOS and KRONOS Phase III trials

AstraZeneca's *Trixeo Aerosphere* (formoterol fumarate/glycopyrronium bromide/budesonide) has been recommended for marketing authorisation in the European Union (EU) for maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid (ICS) and long-acting beta2-agonist (LABA), or a combination of a LABA and a long-acting muscarinic antagonist.

Trixeo Aerosphere, a triple-combination therapy, is approved under the brand name *Breztri Aerosphere* in Japan, China and the US for patients with COPD.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency based its positive opinion on results from the ETHOS Phase III trial in which *Trixeo Aerosphere* showed a statistically significant reduction in the rate of moderate or severe exacerbations compared with dual-combination therapies *Bevespi Aerosphere* (glycopyrronium/formoterol fumarate) and PT009 (budesonide/formoterol fumarate) over 52 weeks.¹

The recommendation for approval was also supported by data from the KRONOS Phase III trial.² In both trials, the safety and tolerability of *Trixeo Aerosphere* were consistent with the profiles of the dual comparators.^{1,2}

Klaus Rabe, Professor of Pulmonary Medicine at the University of Kiel, Director of the Department of Pneumology at Clinic Grosshansdorf, Germany, Lead Investigator of the ETHOS trial and National Co-ordinating Investigator of the KRONOS Phase III trial, said: "Preventing exacerbations is central to the management of chronic obstructive pulmonary disease, as exacerbations may cause irreversible damage and disease progression. The triple-combination therapy, *Trixeo Aerosphere*, has demonstrated significant benefits in reducing moderate or severe exacerbations in patients suffering from this debilitating disease."

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, said: "Chronic obstructive pulmonary disease is now the third leading cause of death globally and affects approximately one in 10 adults over the age of 40 in Europe. *Trixeo Aerosphere* has demonstrated strong clinical benefit when compared with dual-combination therapies and this positive recommendation brings us closer to providing a much-needed new treatment to patients in Europe."

COPD

COPD is a progressive disease which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness.^{3,4,5} It affects an estimated 384 million people⁶ and is the third leading cause of death globally.⁷ In Europe, approximately 10% of adults over the age of 40 have COPD.⁸ Improving lung function, reducing exacerbations and managing daily symptoms such as breathlessness are important treatment goals in the management of COPD.³ A single COPD exacerbation can have a negative impact on lung function,^{9,10} quality of life¹¹ and increase the risk of hospitalisation.¹² Additionally, even one COPD exacerbation that results in hospitalisation increases the risk of death.^{13,14}

ATHENA clinical trial programme

The ETHOS and KRONOS Phase III trials are part of AstraZeneca's ATHENA Phase III clinical trial programme for *Trixeo Aerosphere*, which included more than 15,500 patients globally across 11 trials.

ETHOS is a randomised, double-blinded, multi-centre, parallel-group, 52-week Phase III trial to assess the efficacy and safety of *Trixeo Aerosphere* in symptomatic patients with moderate to very severe COPD and a history of exacerbation(s) in the previous year. The primary endpoint was the rate of moderate or severe exacerbations.¹ Results were published in [The New England Journal of Medicine](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7307000/).¹

KRONOS is a randomised, double-blinded, parallel-group, 24-week, chronic-dosing, multi-centre Phase III trial to assess the efficacy and safety of *Trixeo Aerosphere* in patients with moderate to very severe COPD regardless of whether or not they had an exacerbation in the previous year. The primary endpoints were lung function parameters.² Results were published in [The Lancet Respiratory Medicine](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7307000/).²

Trixeo Aerosphere

fumarate, a LABA, glycopyrronium bromide, a LAMA, with budesonide, an ICS, and delivered in a pressurised metered-dose inhaler.

Trixeo Aerosphere is approved under the brand name *Breztri Aerosphere* in Japan, China and the US for patients with COPD.

Respiratory & Immunology is one of AstraZeneca's three therapy areas and is a key growth driver for the Company.

Building on a 50-year heritage, AstraZeneca is an established leader in respiratory care, across inhaled and biologic medicines. AstraZeneca aims to transform the treatment of asthma and COPD by eliminating preventable asthma attacks across all severities and removing COPD as a leading cause of death through earlier biology-led treatment. The Company's early respiratory research is focused on emerging science involving immune mechanisms, lung damage and abnormal cell-repair processes in disease and neuronal dysfunction.

With common pathways and underlying disease drivers across respiratory and immunology, AstraZeneca is following the science from chronic lung diseases to immunology-driven disease areas. The Company's growing presence in immunology is focused on five mid-to late-stage franchises with multi-disease potential in rheumatology (including systemic lupus erythematosus), dermatology, gastroenterology, and systemic eosinophilic-driven diseases. AstraZeneca's ambition in immunology is to achieve disease control and ultimately clinical remission in targeted immune-driven diseases.

AstraZeneca

AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Twitter [@AstraZeneca](https://twitter.com/AstraZeneca).

Contacts

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