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Breztri approved in the US for asthma as first and only triple therapy for patients 12 years of age and older

Approval based on KALOS and LOGOS Phase III trials demonstrating statistically significant and clinically meaningful benefits of AstraZeneca's single-inhaler fixed-dose triple therapy compared with inhaled dual therapy

Approval is second indication for Breztri beyond COPD

AstraZeneca's fixed-dose triple-combination therapy *Breztri Aerosphere* (budesonide/glycopyrrolate/formoterol fumarate or BGF 320/36/9.6µg) has been approved in the US for the maintenance treatment of asthma in adult and paediatric patients 12 years of age and older. *Breztri* is a single-inhaler that combines the efficacy of corticosteroid/long-acting beta2-agonist (ICS/LABA) medicines with a long-acting muscarinic antagonist (LAMA). *Breztri* (320/18/9.6µg) was approved in the US in 2020 to treat adults with chronic obstructive pulmonary disease (COPD) and was prescribed to more than 6.8 million patients globally in 2025.[1,2]

The approval by the US Food and Drug Administration (FDA) was based on efficacy and safety data from the Phase III KALOS and LOGOS trials investigating *Breztri* in a broad population consisting of patients with asthma, with or without a recent asthma exacerbation.[3] In these trials, *Breztri* demonstrated a statistically significant and clinically meaningful improvement in lung function compared with dual-combination inhaled ICS/LABA.[3] In a key secondary endpoint, *Breztri* also demonstrated a rapid onset of action with a significant improvement from baseline in lung function within five minutes after the first dose.[3] *Breztri* is a maintenance therapy and is not used to relieve sudden breathing problems and will not replace a rescue inhaler.

Njira Lugogo, MD, Clinical Professor, Division of Pulmonary and Critical Care Medicine, Department of Internal Medicine, University of Michigan, said: "Despite the availability of dual maintenance therapy, many patients are still at risk for exacerbations and experience daily breathing difficulties, reduced lung function and the ongoing fear of worsening symptoms. The FDA approval of *Breztri* as the only maintenance triple therapy for people with asthma 12 years of age and older marks a pivotal moment in helping those living with this debilitating disease breathe better, sooner."

Ruud Dobber, Executive Vice President, BioPharmaceuticals Business Unit, AstraZeneca, said: "As the fastest growing fixed-dose triple-combination therapy in COPD, *Breztri* is already improving outcomes for people suffering with COPD, and we are proud to extend its benefits to asthma patients. The FDA's approval of *Breztri* in asthma demonstrates how our innovative science continues to bring new solutions for patients with respiratory diseases."

There are 27 million people living with asthma in the US,[4] around half of whom continue to be uncontrolled on dual therapies, leading to inflammation and muscle tightening in the airway (bronchoconstriction) that cause wheezing, breathlessness, chest tightness, coughing exacerbations and even death.[5-7] Nearly 10 million asthma attacks still occur each year in the US.[4]

Results from KALOS and LOGOS were published in *The Lancet Respiratory Medicine* in February 2026.[3] There were no new safety or tolerability signals identified for *Breztri* in the trials.[3]

Breztri is a single-inhaler fixed-dose triple-combination therapy approved for the treatment of COPD in adults in 90 countries worldwide including the US, EU, China and Japan. Regulatory filings for *Breztri* in asthma are currently under review in other major regions including the EU, Japan and China.

Notes

Asthma

Asthma is a prevalent, chronic respiratory disease affecting as many as 262 million people worldwide,[8] including 27 million in the US.[4] When uncontrolled, inflammation and muscle tightening in the airway (bronchoconstriction) may cause wheezing, breathlessness, chest tightness, coughing, and

even death.[5-7] Many patients remain uncontrolled despite the availability of standard of care medicines and continue to experience significant limitations on lung function and reduced quality of life.[6,7]

KALOS and LOGOS Phase III trials
KALOS and LOGOS were replicate confirmatory, randomised, double-blind, double-dummy, parallel group, multi-centre, 24-to-52-week variable length Phase III trials to assess the efficacy and safety of *Breztri Aerosphere* compared with S*ymbicort* (budesonide/formoterol fumarate, a marketed therapeutic option), PT009 (budesonide/formoterol fumarate in an *Aerosphere* formulation) and the *Symbicort* and PT009 treatment groups combined.[3,9,10] KALOS and LOGOS included approximately 4,300 randomised patients.

The primary endpoints for the two individual trials were a change from baseline in forced expiratory volume in 1 second (FEV_1) area under the curve 0 to 3 hours (AUC_{0-3}) at Week 24 and trough FEV_1 over 12-24 weeks and over 24 weeks.[3,9,10] The primary endpoints and treatment comparisons in the KALOS and LOGOS trials differed according to regulatory submission approaches. In the data package submitted to the US FDA, the primary lung function endpoint was change from baseline in FEV_1 AUC_{0-3} at week 24, and the key secondary endpoint was change from baseline in morning pre-dose trough FEV_1 at week 24, compared to PT009.[3]

Breztri/Trixeo Aerosphere
Budesonide/glycopyrronium/formoterol fumarate or budesonide/glycopyrrolate/formoterol fumarate, is approved under the brand name *Breztri Aerosphere* in Japan, China and the US, and *Trixeo Aerosphere* in the EU, is a single-inhaler, fixed-dose triple-combination of formoterol fumarate, a LABA, glycopyrronium bromide, a long-acting muscarinic antagonist (LAMA), with budesonide, an ICS, and delivered via the *Aerosphere* pMDI. *Breztri/Trixeo Aerosphere* is approved to treat adults with COPD in 90 countries worldwide including the US, EU, China, Japan, and was prescribed to more than 6.8 million patients globally in 2025.[2]

AstraZeneca in Respiratory & Immunology
Respiratory & Immunology, part of AstraZeneca BioPharmaceuticals, is a key disease area and growth driver to the Company.

AstraZeneca is an established leader in respiratory care with a 50-year heritage and a growing portfolio of medicines in immune-mediated diseases. The Company is committed to addressing the vast unmet needs of these chronic, often debilitating, diseases with a pipeline and portfolio of inhaled medicines, biologics and new modalities aimed at previously unreachable biologic targets. Our ambition is to deliver life-changing medicines that help eliminate COPD as a leading cause of death, eliminate asthma attacks and achieve clinical remission in immune-mediated diseases.

AstraZeneca
AstraZeneca (LSE/STO/NYSE: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Diseases, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca's innovative medicines are sold in more than 125 countries and used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Social Media @AstraZeneca.

Contacts
For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

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Matthew Bowden
Company Secretary
AstraZeneca PLC