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Trixeo approved in the EU for the maintenance treatment of asthma

Trixeo is the first and only triple-combination therapy approved in the EU for patients 12 years and older, independent of exacerbation history

AstraZeneca's fixed-dose triple-combination *Trixeo Aerosphere* (budesonide/glycopyrronium/formoterol fumarate dihydrate or BGF (320/28.8/10µg)) has been approved in the European Union (EU) as a maintenance treatment for asthma in patients 12 years of age and older who are not adequately controlled by a combination of a medium dose inhaled corticosteroid (ICS) and long-acting beta2-agonist (LABA). *Trixeo Aerosphere,* marketed as *Breztri Aerosphere* in the US, China and Japan, is a single inhaler that combines the efficacy of ICS/LABA with a long-acting muscarinic antagonist (LAMA).

The approval by the European Commission (EC) follows the positive opinion of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and was based on the positive results from the KALOS and LOGOS Phase III trials. In the trials, *Trixeo* demonstrated statistically significant improvements in lung function compared with combined ICS/LABA comparators.[1] In the pooled analysis of KALOS and LOGOS, *Trixeo* demonstrated a statistically significant reduction in the annualised rate of severe asthma exacerbations versus combined ICS/LABA comparators in a broad population of patients including those with no asthma exacerbations in the previous year.[1]

Alberto Papi, Professor and Chair of Respiratory Medicine at the University of Ferrara, and Director of the Respiratory Unit, CardioRespiratory Department, S. Anna University Hospital, Ferrara, Italy, and primary investigator, said: "Every day, I see patients whose asthma remains uncontrolled despite maintenance treatment, leaving them with persistent symptoms like difficulty breathing and declining lung function and at risk of exacerbations, which can have serious health consequences. The approval of *Trixeo* in Europe as the first triple-combination therapy in a single inhaler for patients 12 years of age and older provides an important new treatment option that has been shown to improve asthma control and reduce future risk of exacerbations, regardless of exacerbation history."

Ruud Dobber, Executive Vice President and President, BioPharmaceuticals Business Unit, AstraZeneca, said: "Today's approval in asthma builds on *Trixeo's* established role in improving outcomes in patients with COPD. This means we can now bring the benefits of a single-inhaler triple-combination therapy to people aged 12 years and older in Europe whose asthma remains uncontrolled on dual inhaled therapy."

In a key secondary endpoint, *Trixeo* demonstrated a rapid onset of action with a significant improvement from baseline in lung function within five minutes after the first dose.[1] *Trixeo* is a maintenance therapy and is not used to relieve sudden breathing problems and will not replace a rescue inhaler. Results from KALOS and LOGOS were published in *The Lancet Respiratory Medicine* in February 2026.[1] There were no new safety or tolerability signals identified for *Trixeo* in the trials.[1]

In Europe, there are nearly 43 million people living with asthma, and every year, about four million more people are newly diagnosed.[2] When uncontrolled on dual therapies, patients can often struggle with symptoms such as wheezing, breathlessness, coughing, exacerbations and even death.[3-5]

Trixeo/Breztri, is also approved in the US and Japan for treatment of asthma and is currently under review in China, as well as other countries. *Trixeo/Breztri* is also approved for the treatment of COPD in adults in 90 countries worldwide including the US, EU, China and Japan.

Notes

Asthma

Asthma is a prevalent, chronic respiratory disease affecting as many as 363 million people worldwide, including nearly 43 million people in Europe.[2,6] Around half of patients 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.[3-5] 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.[4,5]

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/Trixeo Aerosphere* compared with two fixed-dose, dual-combination therapies of budesonide, an ICS, and formoterol fumarate, a LABA: *Symbicort* pressurised metered-dose inhaler (pMDI) and PT009 (in an Aerosphere formulation).[1,7,8] KALOS and LOGOS included approximately 4,300 randomised patients.[7,8]

In the data package submitted to the EMA, in the individual trials, the primary lung function endpoint was change from baseline in morning pre-dose trough FEV_1 over 24 weeks, and the key secondary endpoint was change from baseline in FEV_1 AUC_{0-3} over 24 weeks, versus dual therapy (the ICS/LABA treatment groups combined).[1] The pooled primary endpoint using data from both KALOS and LOGOS trials, and prioritised in the testing procedure, was the rate of severe asthma exacerbations versus dual therapy (ICS/LABA) treatment groups combined.[1] The primary and secondary endpoints and treatment comparisons in the KALOS and LOGOS trials differed according to regulatory submission approaches.[1]

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* (budesonide/glycopyrronium/formoterol fumarate dihydrate) in the EU, as a single-inhaler, fixed-dose triple-combination of formoterol fumarate, a LABA, glycopyrronium bromide, a LAMA, with budesonide, an ICS, and delivered via the *Aerosphere* pMDI.

Breztri/Trixeo is approved in the US, Europe and Japan to treat asthma in patients 12 years of age and older. Regulatory filings for *Breztri/Trixeo* in asthma are currently under review in all other major regions.

Breztri /Trixeo is also approved for the treatment of COPD in more than 90 countries worldwide including the US, EU, China, and Japan, and was prescribed to more than 6.8 million patients globally in 2025.[9]

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
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