RNS Number : 1481H
AstraZeneca PLC
02 May 2025

02 May 2025

Breztri met primary endpoints in KALOS and LOGOS Phase III trials in asthma

Positive high-level results from the Phase III KALOS and LOGOS trials in patients with uncontrolled asthma showed that AstraZeneca's fixed-dose triple-combination therapy *Breztri Aerosphere* (budesonide/glycopyrronium/formoterol fumarate or BGF (320/28.8/9.6µg)) met all primary endpoints, demonstrating a statistically significant and clinically meaningful improvement in lung function compared with dual-combination inhaled corticosteroid/long-acting beta2-agonist (ICS/LABA) medicines.

KALOS and LOGOS were replicate, randomised, double-blind trials designed to investigate *Breztri* as a potential treatment for asthma.[1,2] The trials evaluated the efficacy and safety of *Breztri* versus maintenance treatment with ICS/LABA in adults and adolescents with uncontrolled asthma.[1,2]

Asthma is a common, chronic respiratory disease characterised by inflammation and muscle tightening in the airway (bronchoconstriction), which can make it difficult to breathe.[3] As many as 262 million people worldwide are affected by asthma,[3] and it is estimated that nearly half of those treated with dual therapy remain uncontrolled, which can significantly limit lung function and decrease quality of life.[4,5]

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: "Despite advancements in asthma treatments, millions of patients remain uncontrolled, which can cause frequent breathlessness, coughing and wheezing, significantly impacting their ability to perform daily activities. The results from the KALOS and LOGOS trials are exciting and demonstrate the potential of budesonide/glycopyrronium/formoterol to evolve the standard of care to more effectively treat asthma in a single inhaled triple therapy for patients who remain uncontrolled with dual maintenance therapy."

Sharon Barr, Executive Vice President, BioPharmaceuticals R&D, AstraZeneca, said: "We are excited by the positive results from the KALOS and LOGOS trials, which demonstrate that *Breztri* could help improve the lives of the millions of patients living with asthma. These asthma data build on the well-established profile of *Breztri* in COPD, and we look forward to sharing with regulatory authorities to bring this important medicine to a wider group of patients."

There were no new safety or tolerability signals identified for *Breztri* in KALOS or LOGOS.

Full results from the two Phase III trials will be shared with regulatory authorities and presented at an upcoming medical meeting.

Breztri is an inhaled triple-combination therapy approved for the treatment of chronic obstructive pulmonary disease (COPD) in adults in more than 80 countries worldwide including the US, EU, China and Japan.

Notes

Asthma

Asthma is a prevalent, chronic respiratory disease affecting as many as 262 million people worldwide,[3] including over 25 million in the US.[6] When uncontrolled, inflammation and muscle tightening in the airway (bronchoconstriction) may cause wheezing, breathlessness, chest tightness, coughing, and even death.[3,7] 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.[4,5]

KALOS and LOGOS Phase III trials
KALOS and LOGOS are 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 BGF (320/28.8/9.6µg and 320/14.4/9.6µg) compared with two fixed-dose, dual-combination therapies of budesonide, an ICS, and formoterol fumarate, a LABA: PT009 (in an *Aerosphere* inhaler) and *Symbicort* pressurised metered-dose inhaler (pMDI).[1,2] KALOS and LOGOS included approximately 4,400 randomised patients.

The trial design was optimised to evaluate the 320/28.8/9.6µg dose of BGF. The primary efficacy endpoints for the two individual trials were a change from baseline in forced expiratory volume in 1 second (FEV1) area under the curve 0 to 3 hours (AUC0-3) at Week 24 and trough FEV1 over 12-24 weeks and over 24 weeks.[1,2]

In addition to the two registrational trials (KALOS and LOGOS), two qualifying trials, LITHOS and VATHOS, also met their primary endpoints.[8,9] LITHOS and VATHOS included approximately 1,000 randomised patients.

Breztri/Trixeo Aerosphere
Budesonide/glycopyrronium/formoterol fumarate (BGF), 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 more than 80 countries worldwide including the US, EU, China, Japan, and was prescribed to more than 5.5 million patients globally in 2024.[10]

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/Nasdaq: 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.

References

1. Clinicaltrials.gov. Study to Assess PT010 in Adult and Adolescent Participants with Inadequately Controlled Asthma (KALOS) [Online]. Available at: https://clinicaltrials.gov/study/NCT04609878?limit=25&term=KALOS&rank=1. [Last accessed: May 2025].
2. Clinicaltrials.gov. Study to Assess PT010 in Adult and Adolescent Participants with Inadequately Controlled Asthma (LOGOS) [Online]. Available at: https://clinicaltrials.gov/study/NCT04609904?limit=25&term=LOGOS&rank=4. [Last accessed: Mayl 2025].
3. Global Asthma Network. The Global Asthma Report 2022. [Online]. Available at: http://globalasthmareport.org/resources/Global_Asthma_Report_2022.pdf. [Last accessed: May 2025].
4. Davis J, *et al*. Burden of asthma among patients adherent to ICS/LABA: A real-world study. *J Asthma*. 2019 Mar;56(3):332-340.
5. Buhl R, *et al*. One-year follow up of asthmatic patients newly initiated on treatment with medium- or high-dose inhaled corticosteroid-long-acting β2-agonist in UK primary care settings. *Respir Med*. 2020 Feb: 162:105859.
6. U.S. Centers for Disease Control and Prevention (CDC). Most Recent National Asthma Data. [Online]. Available at: https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm. [Last accessed: May 2025].
7. Fernandes AG, *et al*. Risk factors for death in patients with severe asthma. *J Bras Pneumol*. 2014; 40 (4): 364-372.
8. Clinicaltrials.gov. A 12-week Study to Assess the Efficacy and Safety of Budesonide and Formoterol Fumarate Metered Dose Inhaler Relative to Budesonide Metered Dose Inhaler in Participants with Inadequately Controlled Asthma (LITHOS) [Online]. Available at: https://clinicaltrials.gov/study/NCT05755906?limit=25&term=LITHOS&rank=1. [Last Accessed: May 2025].
9. Clinicaltrials.gov. A 24-Week Efficacy and Safety Study to Assess Budesonide and Formoterol Fumarate Metered Dose Inhaler in Adult and Adolescent Participants with Inadequately Controlled Asthma (VATHOS) [Online]. Available at: https://clinicaltrials.gov/study/NCT05202262?limit=25&term=VATHOS&rank=1. [Last Accessed: May 2025].
10. AstraZeneca Data on File. 2025. REF-270910.

Matthew Bowden
Company Secretary
AstraZeneca PLC