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Tezspire approved in the US for chronic rhinosinusitis with nasal polyps

Approval broadens indication for Tezspire to a second disease characterised by epithelial-driven inflammation

AstraZeneca and Amgen's *Tezspire* (tezepelumab) has been approved in the US for the add-on maintenance treatment of adult and paediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP), a complex epithelial-driven inflammatory condition. *Tezspire* is the first and only biologic that targets thymic stromal lymphopoietin (TSLP) to be approved for CRSwNP.

The approval by the US Food and Drug Administration (FDA) was based on efficacy and safety data from the WAYPOINT Phase III trial, which were presented at the 2025 American Academy of Allergy Asthma & Immunology (AAAAI)/World Allergy Organization (WAO) Joint Congress and simultaneously published in *The New England Journal of Medicine*.[1,2] In the trial, *Tezspire* demonstrated a statistically significant and clinically meaningful reduction in nasal polyp severity, and showed near-elimination of the need for surgery and significant reduction in systemic corticosteroid use vs. placebo.[1,2]

Dr. Joseph Han, Vice Chair of Department of Otolaryngology - Head and Neck Surgery, Old Dominion University, US, and co-primary investigator in the WAYPOINT trial, said: "Over 320 million lives globally are disrupted by chronic rhinosinusitis with nasal polyps. The FDA approval of *Tezspire* brings forward a new treatment option that has demonstrated rapid and sustained symptom improvement, nearly eliminating the need for future surgeries and significantly reducing systemic steroid use. By targeting TSLP at the top of the inflammatory cascade, *Tezspire* offers a novel option for patients who continue to endure the disruption of this disease despite available treatments."

Kenneth Mendez, President and CEO of the Asthma and Allergy Foundation of America (AAFA), said: "Chronic rhinosinusitis with nasal polyps is a persistent and often-overlooked disease that can significantly impact daily life, robbing patients of their ability to breathe without congestion and full sense of smell. This approval introduces an innovative treatment option for patients with the potential to help address the ongoing cycle of debilitating symptoms, surgeries and systemic steroid use."

Ruud Dobber, Executive Vice President, BioPharmaceuticals Business Unit, AstraZeneca said: "Today's approval of *Tezspire* in chronic rhinosinusitis with nasal polyps expands the reach of this innovative treatment option to patients living with an epithelial-driven inflammatory disease beyond severe asthma. Building on the widespread, established use of *Tezspire* in severe asthma, this exciting milestone now reinforces its unique mechanism of action across both the upper and lower airways andreflects our commitment to transforming care for patients who face the daily burden of chronic respiratory and immune-mediated diseases."

CRSwNP affects up to approximately 320 million people worldwide and is a complex epithelial-driven inflammatory condition characterised by persistent inflammation and benign polyp growths within the nasal cavity. People living with CRSwNP commonly experience airflow obstruction and symptoms including congestion and an impaired sense of smell.[3-7] For many patients, current therapies such as systemic and intranasal corticosteroids and repeated sinus surgeries do not offer lasting relief.[4]

The safety profile and tolerability of *Tezspire* in the WAYPOINT trial was generally consistent with the known profile of the medicine.[1] The most frequently reported adverse events in the trial were COVID-19, nasopharyngitis and upper respiratory tract infection.[1]

The Committee for Medicinal Products for Human Use (CHMP) recently adopted a positive opinion for the approval of *Tezspire* in the EU for treatment of CRSwNP.[8] Regulatory applications are currently under review in the EU, China, Japan and several other countries.

Tezspire is currently approved for the treatment of severe asthma in the US, EU, Japan and more than 60 countries across the globe.[9-11]

Notes

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP (nasal polyps))

CRSwNP is a complex inflammatory disorder, characterised by persistent inflammation of the nasal mucosa accompanied by benign growths, called nasal polyps.[3,4] Nasal polyps can block nasal passages and lead to breathing problems, difficulty in sense of smell, nasal discharge, facial pain, sleep disturbance and other adverse effects on quality of life. [5-7]

Epithelial dysfunction and inflammation are important characteristics of chronic rhinosinusitis and impede the ability of the epithelium to act as a physical and immunological barrier against the external environment.[12,13] Thymic stromal lymphopoietin (TSLP) is an epithelial cytokine that has been implicated in shared pathophysiological processes underlying severe asthma and CRSwNP.[12,13]

Current treatments for CRSwNP includeintranasal and/or systemic corticosteroids, surgery and biologics.[4,7,14-19]

Phase III WAYPOINT trial

WAYPOINT was a double-blind, multi-centre, randomised, placebo-controlled, parallel group trial designed to evaluate the efficacy and safety of tezepelumab in adults with uncontrolled CRSwNP.[1,2,20]

designed to evaluate the efficacy and safety of tezepelumab in adults with uncontrolled CRSwNP. Participants received tezepelumab or placebo, administered via subcutaneous injection. The trial also included a post-treatment follow-up period of 12-24 weeks for participants who completed the 52-week treatment period.[1,20]

The co-primary endpoints of the trial were change from baseline in total nasal polyp size, measured by the endoscopic total Nasal Polyp Score, and change from baseline in bi-weekly mean nasal congestion, measured by the participant reported Nasal Congestion Score evaluated as part of the daily Nasal Polyposis Symptom Diary.[1,20] Key secondary endpoints included loss of smell; improvement in disease specific health-related quality of life as measured by SinoNasal Outcome Test (SNOT-22) score; Lund-Mackay score; time to surgery decision and/or systemic corticosteroids for nasal polyposis; time to nasal polyposis surgery decision; time to systemic corticosteroids for nasal polyposis; Nasal Polyposis Symptom Diary total symptom score and, in the population with co-morbid asthma, pre-bronchodilator FEV1 at Week 52.[1,20]

Tezepelumab
Tezepelumab is being developed by AstraZeneca in collaboration with Amgen as a first-in-class human monoclonal antibody that inhibits the action of thymic stromal lymphopoietin (TSLP), a key epithelial cytokine that sits at the top of multiple inflammatory cascades and is critical in the initiation and persistence of allergic, eosinophilic and other types of epithelial inflammation associated with severe asthma, CRSwNP and other inflammatory diseases.[12,13]

TSLP is released by the epithelium in response to environmental triggers (including allergens, viruses and other airborne particles) associated with asthma, CRSwNP, chronic obstructive pulmonary disease (COPD), eosinophilic esophagitis (EoE) and other diseases.[13,21] Across these disease states, the expression of TSLP is increased and correlates with disease severity.[7,11]

Tezspire is approved as a single-use pre-filled syringe and auto-injector for self-administration in the US and EU.[9-11] Since 2021, over 100,000 patients have been treated with *Tezspire* for severe asthma.[22]

Beyond CRSwNP, *Tezspire* is also being explored in Phase III trials in COPD and EoE.[23,24] In October 2021, *Tezspire* was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of EoE.[25]

Amgen Collaboration
The 2012 Collaboration Agreement between Amgen and AstraZeneca has been amended and updated over time. For *Tezspire*, both companies continue to share costs and profits equally after payment by AstraZeneca of a mid single-digit inventor royalty to Amgen. AstraZeneca continues to lead development and Amgen continues to lead manufacturing. All aspects of the collaboration are under the oversight of joint governing bodies. Under the agreement, Amgen and AstraZeneca jointly commercialise *Tezspire* in the US. Amgen records product sales in the US, with AZ recording its share of US profits as Collaboration Revenue. Outside of the US, AstraZeneca records product sales, with Amgen recording profit share as Other/Collaboration revenue.

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
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