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Tezspire recommended for approval in the EU by CHMP for chronic rhinosinusitis with nasal polyps

Recommendation based on WAYPOINT Phase III trial results showing Tezspire reduced nasal polyp severity and nasal congestion, nearly eliminated the need for surgery and significantly reduced systemic corticosteroid use vs. placebo

AstraZeneca and Amgen's *Tezspire* (tezepelumab) has been recommended for approval in the European Union (EU) for the treatment of adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP).

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) based its positive opinion on results 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 WAYPOINT trial, *Tezspire* demonstrated a statistically significant and clinically meaningful reduction in nasal polyp severity, as measured by the co-primary endpoints; Nasal Polyp Score (NPS) by -2.08 (95% CI: -2.40, -1.76; p<0.001) and nasal congestion (measured by participant-reported Nasal Congestion Score [NCS]) by -1.04 (95% CI: -1.21, -0.87; p<0.001) at week 52 compared to placebo.[1,2] Data also showed *Tezspire* enabled near-complete elimination of the need for surgery (98%) and significantly reduced the need for systemic corticosteroid treatment (89%) compared to placebo.[2]

Dr. Oliver Pfaar, Chair of the Section Rhinology and Allergy, ENT-Department, University Hospital Marburg, Philipps-Universität Marburg in Marburg, Germany and investigator in the WAYPOINT trial, said: "Chronic rhinosinusitis with nasal polyps is a challenging condition. For many patients, current therapies don't offer lasting relief causing a cycle of repeat surgeries and ongoing treatment with oral corticosteroids, which can result in serious side effects. This positive CHMP recommendation is very encouraging and if approved, tezepelumab will provide patients and clinicians in Europe with an important new treatment option that has demonstrated rapid, sustained symptom relief."

Ruud Dobber, Executive Vice President and President, BioPharmaceuticals Business Unit, AstraZeneca, said: "The CHMP recommendation brings us closer to offering *Tezspire* to patients across the EU who face the daily challenges of this disruptive and difficult-to-treat disease. The unique way *Tezspire* works means it addresses the multiple drivers of epithelial-driven inflammation associated with chronic rhinosinusitis with nasal polyps. This pivotal milestone builds upon *Tezspire's* foundational impact in severe asthma and reinforces our commitment to transforming respiratory care."

CRSwNP is a chronic inflammatory condition characterised by persistent inflammation and benign polyp growths within the nasal cavity that can obstruct airflow and impair sense of smell, taste and sleep.[3-7] This condition affects up to roughly 320 million people worldwide.[7] Nearly half of the patients diagnosed with CRSwNP in Europe remain uncontrolled, and for many patients, current therapies such as systemic corticosteroids and repeated sinus surgeries do not offer lasting relief.[4,8]

The safety profile and tolerability of tezepelumab in the WAYPOINT trial were consistent with the known profile of the medicine.[2]

Regulatory applications are currently under review in the US, China, Japan and several other countries based on the WAYPOINT trial. *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.[13]

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

Phase III WAYPOINT trial

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

received tezepelumab or placebo, administered via subcutaneous injection.[1,2,20] The trial also included a post-treatment follow-up period of 12-24 weeks for participants who completed the 52-week treatment period.[2,20]

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.[2,20] 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.[2,20]

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] Across these disease states, the expression of TSLP is increased and correlates with disease severity.[7,12]

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. [21]

Beyond CRSwNP, *Tezspire* is also being explored in Phase III trials in COPD and EoE.[22,23] In October 2021, *Tezspire* was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of EoE.

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 will jointly commercialise *Tezspire* in the US. Amgen will record product sales in the US, with AZ recording its share of US profits as Collaboration Revenue. Outside of the US, AstraZeneca will record 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
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Contacts
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