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Tezspire approved in the EU for chronic rhinosinusitis with nasal polyps

Approval based on WAYPOINT Phase III results demonstrating reduced nasal polyp severity and nasal congestion, near-elimination of the need for surgery and significantly reduced systematic corticosteroid use vs. placebo

AstraZeneca and Amgen's *Tezspire* (tezepelumab) has been approved in the European Union (EU) as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP) who have not adequately responded to standard therapy (systemic corticosteroids and/or surgery).

The approval by the European Commission (EC) follows the positive opinion of the Committee for Medicinal Products for Human Use (CHMP) and was based on positive results from the WAYPOINT Phase III trial, 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*.[1-3] 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.[2,3]

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 challenging to treat, as it often requires repeat surgeries and ongoing treatment with systemic corticosteroids, both of which can result in serious side effects. Tezepelumab's approval in the EU means clinicians have an innovative new treatment option that has shown a clinically meaningful and significant reduction in nasal polyp size, symptom severity and the need for surgery and systemic corticosteroid use compared to placebo."

Ruud Dobber, Executive Vice President and President, BioPharmaceuticals Business Unit, AstraZeneca, said: "In Europe, we know that nearly half of patients with chronic rhinosinusitis with nasal polyps remain uncontrolled despite treatment with standard of care, which is why today's approval of *Tezspire* is such an important step forward in this challenging disease. This approval broadens *Tezspire's* benefits beyond severe asthma and reinforces *Tezspire's* innovative mechanism of action that targets thymic stromal lymphopoietin (TSLP), uniquely addressing epithelial-driven inflammation at its source."

CRSwNP affects approximately 320 million people worldwide and is a complex disease characterised by epithelial-driven inflammation and benign polyp growths within the nasal cavity.[4,5] 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.[5,6] People living with CRSwNP commonly experience airflow obstruction and symptoms including congestion and an impaired sense of smell.[5,7-9]

The safety profile and tolerability of *Tezspire* in the WAYPOINT trial was generally consistent with the known profile of the medicine. The most frequently reported adverse events in the trial were COVID-19, nasopharyngitis and upper respiratory tract infection.[2]

Tezspire was recently approved in the US for the add-on maintenance treatment of adult and paediatric patients aged 12 years and older with inadequately controlled CRSwNP,[10] and regulatory applications are currently under review in China, Japan and several other countries. *Tezspire* is also approved for severe asthma in the US, EU, Japan and more than 60 countries across the globe.[10-12]

Notes

Chronic Rhinosinusitis with Nasal Polyps
CRSwNP is a complex inflammatory disorder, characterised by persistent inflammation of the nasal mucosa accompanied by benign growths, called nasal polyps.[4,5] 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.[7-9]

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.[4,13-15] Thymic stromal lymphopoietin (TSLP) is an epithelial cytokine that has been implicated in shared pathophysiological processes underlying severe asthma and CRSwNP.[14,15]

Current treatments for CRSwNP include intranasal and/or systemic corticosteroids, surgery and biologics.[5,9,16-21]

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.[2,3,22] Participants received tezepelumab or placebo, administered via subcutaneous injection.[2,3,22] The trial also included a post-treatment follow-up period of 12-24 weeks for participants who completed the 52-week treatment period.[2,22]

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.[2,22] 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

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.[2,22]

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.[14,15]

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.[15,23] Across these disease states, the expression of TSLP is increased and correlates with disease severity.[24,25]

Tezspire is approved as a single-use pre-filled syringe and auto-injector for self-administration in the US and EU.[10,11] Since 2021, over 100,000 patients have been treated with *Tezspire* for severe asthma.[26]

Beyond CRSwNP, *Tezspire* is also being explored in Phase III trials in COPD and EoE.[27,28] In October 2021, *Tezspire* was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of EoE.[29]

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

References

1. AstraZeneca news release. Tezspire recommended for approval in the EU by CHMP for chronic rhinosinusitis with nasal polyps. Available at: https://www.astrazeneca.com/media-centre/press-releases/2025/tezspire-recommended-for-approval-in-eu-for-crswnp.html. Accessed October 2025.
2. Lipworth, BJ, Han JK, et al. Tezepelumab in adults with severe, uncontrolled CRSwNP. *N Engl J Med.* 2025;392(12):1178-1188.
3. Lipworth, BJ, Han JK, et al. Efficacy and safety of tezepelumab in adults with severe chronic rhinosinusitis with nasal polyps: results from the Phase 3 WAYPOINT Study. [Late breaking oral presentation]. Presented at the American Academy of Allergy, Asthma & Immunology/World Allergy Organization Joint Congress 2025 (28 February - 03 March).
4. Bachert C, et al. Phenotypes and Emerging Endotypes of Chronic Rhinosinusitis. *J Allergy Clin Immunol Pract*. 2016;4(4):621-628.
5. Del Toro E, Portela J. Nasal Polyps. [Updated 2023 Jul 31]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560746/. Accessed: October 2025.
6. Viskins A, et al. Multiple reasons underlaying uncontrolled disease in the majority of chronic rhinosinusitis patients. *Front Allergy.* 2022;13;3:1048385.
7. Stevens WW, et al. Chronic Rhinosinusitis with Nasal Polyps. *J Allergy Clin Immunol Pract*. 2016;4(4):565-572.
8. Abdalla S, et al. Prevalence of sinonasal outcome test (SNOT-22) symptoms in patients undergoing surgery for chronic rhinosinusitis in the England and Wales National prospective audit. *Clin Otolaryngol*. 2012;37(4):276-282.
9. Chen S, et al. Systematic literature review of the epidemiology and clinical burden of chronic rhinosinusitis with nasal polyposis. *Curr Med Res Opin*. 2020;36(11):1897-1911.
10. Tezspire (tezepelumab) US prescribing information. Available at: https://drd9vrdh9yh09.cloudfront.net/50fd68b9-106b-4550-b5d0-12b045f8b184/e306dc06-d580-4457-b15f-9f28545ad63a/e306dc06-d580-4457-b15f-9f28545ad63a_viewable_rendition__v.pdf. Accessed: October 2025.
11. Tezspire (tezepelumab) Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/tezspire-epar-product-information_en.pdf. Accessed: October 2025.
12. AstraZeneca news release. Tezspire approved in Japan for the treatment of severe asthma. Available at: https://www.astrazeneca.com/media-centre/press-releases/2022/tezspire-approved-in-japan-for-severe-asthma.html. Accessed: October 2025.
13. Jong-Gyun J, et al. Unraveling the Role of Epithelial Cells in the Development of Chronic Rhinosinusitis. *Int J Mol Sci*. 2023;24(18):14229.
14. Corren J, et al. Tezepelumab in adults with uncontrolled asthma. *N Engl J Med*. 2017;377:936-946.
15. Varricchi G, et al. Thymic Stromal Lymphopoietin Isoforms, Inflammatory Disorders, and Cancer. *Front Immunol*. 2018;9:1595.
16. Xolair (omalizumab) Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/xolair-epar-product-information_en.pdf. Accessed: October 2025.
17. Xolair (omalizumab) US prescribing information. Available at: https://www.gene.com/download/pdf/xolair_prescribing.pdf. Accessed: October 2025.

18. Nucala (mepolizumab) Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/nucala-epar-product-information_en.pdf. Accessed: October 2025.
19. Nucala (mepolizumab) US prescribing information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761122s006,125526s018lbl.pdf. Accessed: October 2025.
20. Dupixent (dupilumab) Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/dupixent-epar-product-information_en.pdf. Accessed: October 2025.
21. Dupixent (dupilumab) US prescribing information. Available at: https://www.regeneron.com/downloads/dupixent_fpi.pdf. Accessed: October 2025.
22. Clinicaltrials.gov. Efficacy and Safety of Tezepelumab in Participants With Severe Chronic Rhinosinusitis With Nasal Polyposis (WAYPOINT). Available at: https://clinicaltrials.gov/ct2/show/NCT04851964. Accessed: October 2025.
23. Zhang M, et al. Hypoxia induces the production of epithelial-derived cytokines in eosinophilic chronic rhinosinusitis with nasal polyps. *Int Immunopharmacol*. 2023;121:110559.
24. Li Y, *et al*. Elevated Expression of IL-33 and TSLP in the Airways of Human Asthmatics In Vivo: A Potential Biomarker of Severe Refractory Disease. *J Immunol*. 2018;200: 2253-2262.
25. Ying, S, O'Connor, B, Ratoff, J, et al. Thymic stromal lymphopoietin expression is increased in asthmatic airways and correlates with expression of Th2-attracting chemokines and disease severity. J Immunol 2005;174:8183-8190.
26. AstraZeneca Data on File. 2025. REF-278452.
27. Clinicaltrials.gov. Tezepelumab COPD Exacerbation Study (COURSE). Available at: https://clinicaltrials.gov/ct2/show/NCT04039113. Accessed: October 2025.
28. Clinicaltrials.gov. Efficacy and Safety of Tezepelumab in Patients with Eosinophilic Esophagitis (CROSSING). Available at: https://clinicaltrials.gov/study/NCT05583227. Accessed: October 2025.
29. AstraZeneca news release. Tezepelumab granted Orphan Drug Designation in the US for eosinophilic esophagitis. Available at: https://www.astrazeneca.com/media-centre/press-releases/2021/tezepelumab-granted-orphan-drug-designation-in-the-us-for-eosinophilic-esophagitis.html. Accessed: October 2025.

Matthew Bowden
Company Secretary
AstraZeneca PLC