

PRESS RELEASE

Novartis receives European Commission approval for Cosentyx® in polymyalgia rheumatica (PMR)

- *Cosentyx® (secukinumab) becomes first and only IL-17A inhibitor approved in Europe for adults with PMR,¹ a common inflammatory rheumatic disease with limited advanced treatment options²⁻⁶*
- *Approval based on Phase III REPLENISH trial showing Cosentyx doubled sustained remission rates vs placebo at Week 52; safety results consistent with established Cosentyx profile⁷*
- *Additional regulatory reviews of Cosentyx in PMR ongoing globally, including in US and Japan*

Basel, October 21, 2026 – Novartis announced today that the European Commission (EC) has approved Cosentyx® (secukinumab) for the treatment of adults with polymyalgia rheumatica (PMR) who have had an inadequate response to glucocorticoids or who experience relapse during glucocorticoid taper. With this approval, Cosentyx becomes the first and only interleukin-17A (IL-17A) inhibitor approved in Europe for adults with PMR.¹

PMR is a common inflammatory rheumatic disease in adults aged over 50, characterized by acute pain and stiffness in the shoulders, neck, and hips.² It is particularly prevalent among people of Northern European descent.² Despite the considerable burden of symptoms on patients, advanced treatment options have remained limited.²⁻⁶ The current standard of care involves prolonged steroid use, which is associated with high relapse rates and significant adverse outcomes.²⁻⁶

“The approval of secukinumab marks an important advancement for people living with PMR and has the potential to transform how we manage this disease beyond prolonged steroid use alone,” said Prof. Christian Dejaco, Director, Department of Rheumatology, South Tyrol Health Trust, Bruneck, Italy. “Its ability to help patients achieve sustained disease control while tapering steroids, together with its established safety profile, may help address a longstanding challenge in PMR care.”

Supported by data from the Phase III REPLENISH trial, the Cosentyx recommended dose for adults with PMR is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing, in combination with a tapering course of glucocorticoids, after which Cosentyx can be continued as monotherapy. Based on clinical response, the maintenance dose can be increased to 300 mg.^{7,8}

“People living with PMR need treatment options that can help deliver lasting disease control, prevent relapses and support better long-term outcomes,” said Patrick Horber, President, International, Novartis. “The approval of Cosentyx in PMR marks an important step forward for patients who continue to face significant challenges with long-term disease management. This milestone adds to the meaningful progress Cosentyx has already brought to many people living with immune-mediated diseases.”

About Cosentyx

Cosentyx is a fully human biologic that directly inhibits interleukin-17A, an important cytokine involved in the inflammation underlying multiple immune-mediated inflammatory diseases.⁹ It is approved for use in adults with psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and hidradenitis suppurativa (HS).⁹⁻¹¹ Cosentyx is also approved for use in pediatric patients, including those with PsO, juvenile idiopathic arthritis subtypes such as juvenile psoriatic arthritis

(JPsA) and enthesitis-related arthritis (ERA), and in the U.S. for pediatric patients aged 12 years and older with moderate to severe HS and juvenile AS.^{9–16}

About the REPLENISH trial

The REPLENISH trial (NCT05767034) is a global Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study conducted across 27 countries, evaluating the efficacy and safety of Cosentyx in patients with polymyalgia rheumatica (PMR). Patients were randomized into three treatment arms: Cosentyx 300 mg, Cosentyx 150 mg, or placebo, all in combination with a 24-week steroid taper regimen. The primary endpoint of the trial was to assess whether Cosentyx 300 mg s.c. plus a 24-week steroid taper is superior to placebo plus a 24-week steroid taper in achieving sustained remission at Week 52. Key secondary endpoints included the proportion of patients achieving complete sustained remission at Week 52, the adjusted annual cumulative steroid dose, and the time to first use of escape or rescue treatment through Week 52.¹⁷

About polymyalgia rheumatica (PMR)

Polymyalgia rheumatica (PMR) is a common inflammatory rheumatic disease in adults aged 50 years and older, typically characterized by acute pain and stiffness in the shoulders, neck, and hips.² Relapses are frequent, affecting up to 40% of patients in the first year.⁴ Long-term steroid use is the current standard of care and carries significant risks, including osteoporosis and diabetes.¹⁸ Beyond physical complications, PMR substantially impairs quality of life through pain, fatigue, restricted mobility, and fear of relapse.^{4,19,20}

About Novartis Immunology

At Novartis, we're advancing bold science with the goal of bringing relief and a renewed sense of hope to people living with complex, and often overlooked autoimmune and immune-mediated diseases, so they can reclaim their lives. Building on our legacy of first-in-class innovation across rheumatology, dermatology and allergy, and a diverse industry-leading pipeline, we're committed to shaping what's next in Immunology.

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to, the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

About Novartis

Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 300 million people worldwide.

Reimagine medicine with us: Visit us at www.novartis.com and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

References

1. European Medicines Agency. Search results for "polymyalgia rheumatica." European Medicines Agency. https://www.ema.europa.eu/en/search?search_api_fulltext=polymyalgia%20rheumatica [Last Accessed: October 2026].
2. Espígol-Frigolé G, Dejaco C, Mackie SL, et al. Polymyalgia rheumatica. *Lancet*. 2023;402(10411):1459–1472.
3. Gabriel SE, Sunku J, Salvarani C, et al. Adverse outcomes of antiinflammatory therapy among patients with polymyalgia rheumatica. *Arthritis Rheum*. 1997;40(10):1873–1878.
4. Floris A, Piga M, Chessa E, et al. Long-term glucocorticoid treatment and high relapse rate remain unresolved issues in the real-life management of polymyalgia rheumatica: a systematic literature review and meta-analysis. *Clin Rheum*. 2022;41(1):19–31.
5. Regeneron Pharmaceuticals, Inc.; Sanofi. Kevzara® (sarilumab) injection, for subcutaneous use: US prescribing information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761037s013lbl.pdf [Last Accessed: October 2026].
6. European Medicines Agency. Kevzara: EPAR product information. https://www.ema.europa.eu/en/documents/product-information/kevozara-epar-product-information_en.pdf [Last Accessed: October 2026].
7. Stone JH, Buttgerit F, Saraux A, et al. Secukinumab in polymyalgia rheumatica. *N Eng J Med*. 2026;395(7):637–647.
8. Dejaco C, et al. *Secukinumab in polymyalgia rheumatica: Results of the phase 3 REPLENISH trial*. Oral presentation presented at European Congress of Rheumatology (EULAR) 2026; June 3–6, 2026; London, UK. #OP0116.
9. Girolomoni G, Mrowietz U, Paul C. Psoriasis: rationale for targeting interleukin-17. *Br J Dermatol*. 2012;167(4):717–724.
10. Novartis Europharm Limited. Cosentyx® (secukinumab): Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/cosentyx-epar-product-information_en.pdf [Last Accessed: October 2026].
11. Novartis Cosentyx shows clinically meaningful symptom improvements in patients with hidradenitis suppurativa. [Press release]. Available at: <https://www.novartis.com/news/media-releases/novartis-cosentyx-shows-clinically-meaningful-symptom-improvements-patients-hidradenitis-suppurativa-pivotal-phase-iii-trials> [Last Accessed: October 2026].
12. Novartis Cosentyx receives FDA approval for treatment of children and adolescents with moderate to severe plaque psoriasis [Press release]. Available at: <https://www.novartis.com/news/media-releases/novartis-cosentyx-receives-fda-approval-treatment-children-and-adolescents-moderate-severe-plaque-psoriasis> [Last Accessed: October 2026].
13. Novartis Cosentyx receives FDA approval for the treatment of children and adolescents with enthesitis-related arthritis and psoriatic arthritis. [Press release]. Available at: <https://www.novartis.com/news/media-releases/novartis-cosentyx-receives-fda-approval-treatment-children-and-adolescents-enthesitis-related-arthritis-and-psoriatic-arthritis> [Last Accessed: October 2026].
14. Novartis Cosentyx receives positive CHMP opinion for expanded use in childhood arthritic conditions. [Press release]. Available at: <https://www.novartis.com/news/media-releases/novartis-cosentyx-secukinumab-receives-positive-chmp-opinion-expanded-use-childhood-arthritic-conditions> [Last Accessed: October 2026].
15. Novartis Cosentyx® receives FDA approval for pediatric patients aged 12+ with moderate to severe hidradenitis suppurativa. [Press release]. Available at: <https://www.novartis.com/news/media-releases/novartis-cosentyx-receives-fda-approval-pediatric-patients-aged-12-moderate-severe-hidradenitis-suppurativa> [Last Accessed: October 2026].
16. Cosentyx. Prescribing information. Novartis Pharmaceuticals Corp. Available at: https://www.novartis.com/us-en/sites/novartis_us/files/cosentyx.pdf [Last Accessed: October 2026].
17. ClinicalTrials.gov. Phase III Study of Efficacy and Safety of Secukinumab Versus Placebo, in Combination With Glucocorticoid Taper Regimen, in Patients With Polymyalgia Rheumatica (PMR) (REPLENISH). NCT05767034. Available at: <https://clinicaltrials.gov/study/NCT05767034> [Last Accessed: October 2026].
18. Mazzantini M, Torre C, Miccoli M, et al. Adverse Events During Longterm Low-dose Glucocorticoid Treatment of Polymyalgia Rheumatica: A Retrospective Study. *J Rheum*. 2012;39(3):552–557.
19. Hutchings A, Hollywood J, Lamping DL, et al. Clinical Outcomes, Quality of Life, and Diagnostic Uncertainty in the First Year of Polymyalgia Rheumatica. *Arthritis Rheum*. 2007;57(5):803–809.
20. Mackie SL, Arun P, Padmanabhan V, et al. Patient perspectives on life impact and unmet needs in giant cell arteritis and polymyalgia rheumatica: insights from social media. *Rheumatol Adv Pract*. 2025;10(1):rkaf140.

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