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PRESS RELEASE

Novartis Cosentyx® becomes first and only FDA-approved anti-IL-17 biologic for people with polymyalgia rheumatica (PMR)

- *Cosentyx® (secukinumab) doubled sustained remission rates and demonstrated steroid-sparing effects vs placebo in Phase III trial*[1]
- *Approval marks 11th US indication for Cosentyx, building on its decade-long established efficacy and safety profile across immune-mediated diseases*[1]
- *Cosentyx PMR indication already approved in EU; additional regulatory reviews ongoing, including in Japan*

Basel, November 17, 2026 – Novartis today announced that the US Food and Drug Administration (FDA) approved Cosentyx® (secukinumab) 150 mg for the treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.[1] Cosentyx is the first and only anti-interleukin-17 (anti-IL-17) biologic approved for people living with PMR, a common inflammatory disease that primarily affects adults over 50, providing a new treatment option beyond long-term steroid use—the current standard of care, which may be associated with significant side effects and risks.[1-5]

“The FDA approval of secukinumab in PMR marks a significant advancement for patients and physicians. Patients with PMR are at increased risk of poor outcomes related to steroids, and the prospect of months or years of additional steroids is disheartening,” said Prof. John Stone, MD, MPH, Professor of Medicine, Harvard Medical School, Massachusetts General Hospital, and global principal investigator for the REPLENISH trial. “For too long, treatment options beyond glucocorticoids have been limited. In the Phase III REPLENISH trial, secukinumab doubled the likelihood of sustained remission while helping patients taper off steroids, which should be the goal of PMR treatment.”

In the United States, there are approximately 966,000 people living with PMR—a disease characterized by acute pain and stiffness in the shoulders, neck, and hips.[2,6] PMR is commonly treated with steroids, but relapses are frequent, affecting up to 40% of patients in the first year.[4] Long-term steroid use increases the risk of osteoporosis, cardiovascular disease, and diabetes.[3] The approval of Cosentyx as the first anti-IL-17 biologic indicated for people with PMR offers rheumatologists an alternative to long-term steroid use based on more than a decade of clinical experience across immune-mediated diseases.[1]

“PMR can make remarkably ordinary things hard: getting out of bed, getting dressed, lifting your arms, getting through the day. For years, patients have had too few treatment options,” said Seth Ginsberg, Co-Founder and President, Global Healthy Living Foundation and CreakyJoints. “The approval of secukinumab offers patients and their clinicians a new therapeutic option and the opportunity for more individualized care.”

“For more than a decade, Cosentyx has helped redefine what’s possible for people living with immune-mediated diseases, delivering meaningful outcomes across multiple conditions,” said Victor Bultó, President, US, Novartis. “With this approval in PMR, our 11th US indication for Cosentyx, we are expanding those benefits to a community that has had limited treatment options for far too long. This milestone reflects our commitment to continually investigate where our medicines can help patients most, extending the impact of proven innovations to new areas of significant unmet need.”

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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. It is approved worldwide for use in adults with psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), hidradenitis suppurativa (HS), and polymyalgia rheumatica (PMR).[1,7-9] 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 for juvenile AS.[1,10,11]

About the REPLENISH trial
This latest FDA approval is based on results from the pivotal Phase III REPLENISH trial (NCT05767034), 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).[12]

Patients were randomized into three treatment arms: Cosentyx 300mg, Cosentyx 150mg, or placebo, all in combination with a 24-week steroid taper regimen.[12] The data were published in the *New England Journal of Medicine* and simultaneously presented at the 2026 European Alliance of Associations for Rheumatology (EULAR) Congress on June 3, 2026.[13,14]

- The primary endpoint was met, with adults with PMR treated with Cosentyx 150 mg achieving sustained remission at twice the rate of those on placebo (40.5% vs 20.5%) at Week 52, following a 24-week steroid tapering.[1,13]
- 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.[13]
- Safety profile in PMR trial remained consistent with the established Cosentyx profile.[1,13]
- Serious adverse events occurred in 15.9% of the patients in the Cosentyx 150 mg group and in 14.2% of those in the placebo group. [13]
- Patients on Cosentyx 150 mg experienced an increased proportion of hypersensitivity reactions (including eczema, dermatitis, rash and urticaria) and urinary tract infections (UTI) vs. placebo (14% vs. 9%, and 13% vs. 7%, respectively). One patient in the Cosentyx 150 mg group experienced a serious event of UTI, and a fatal case of cryptococcal meningitis occurred in a patient treated with Cosentyx.[1,13]

Novartis also filed these data for regulatory review in Japan, in addition to other countries.

About polymyalgia rheumatica (PMR)
Polymyalgia rheumatica (PMR) is a common inflammatory 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. Long-term steroid use is the current standard of care and carries significant risks, including osteoporosis and diabetes.[3,4] Beyond physical complications, PMR substantially impairs quality of life through pain, fatigue, restricted mobility, and fear of relapse.[2,15,16]

About Novartis in 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 other 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.

Disclaimer
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "look forward," or similar expressions, or by express or implied discussions regarding: potential new products; potential new indications for existing products; potential product launches or potential future revenues from any such products; results of ongoing clinical trials; or potential future, pending or announced transactions; potential future sales or earnings; strategy, plans, expectations or intentions, including discussions regarding our continued investment into new R&D capabilities and manufacturing; or our capital structure. You should not place undue reliance on these statements.

Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations could be affected by, among other things, uncertainties concerning: global healthcare cost containment, including ongoing government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; the success of our key products, commercial priorities and strategy; research and development of new products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products; our ability to realize the strategic benefits, operational efficiencies or opportunities expected from our external business opportunities; the development or adoption of new technologies, including artificial intelligence, and new business models; potential significant breaches of information security or disruptions of our information technology systems; actual or potential legal proceedings, including regulatory actions or delays or government regulation related to the products and pipeline products described in this press release; safety, quality, data integrity, or manufacturing issues; major macroeconomic and geo- and socio-political developments, including the impact of any potential tariffs on our products or the impact of war in certain parts of the world; future global exchange rates; future demand for our products; and other risks and factors referred to in Novartis AG's most recently filed Form 20-F and in subsequent reports filed with, or furnished 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**.

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