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PRESS RELEASE

Novartis receives positive CHMP opinion for Cosentyx® in polymyalgia rheumatica (PMR)

- *If approved, Cosentyx (secukinumab) will be first IL-17A inhibitor licensed in Europe for adults with polymyalgia rheumatica (PMR), providing new treatment option after steroids*[1]
- *Recommendation based on data showing Cosentyx doubled sustained remission rates and delivered steroid sparing effects vs placebo; safety was consistent with established Cosentyx profile*[2]
- *Despite being a common inflammatory rheumatic disease in people over 50, there are limited advanced treatments for PMR; extended use of steroids is associated with poor outcomes*[3-7]

Basel, September 18, 2026 – Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending marketing authorization for Cosentyx® (secukinumab) in polymyalgia rheumatica (PMR).[8] The opinion supports Cosentyx use for treatment of PMR in adults who have had an inadequate response to steroids or who experience relapse during steroid taper.[8] If approved, Cosentyx would be the first interleukin-17A (IL-17A) inhibitor approved in Europe for people living with PMR, a disease with very limited advanced treatment options.[1,3-7]

“The introduction of Cosentyx to the PMR space represents a major advancement for patients and clinicians, providing an effective treatment option while also reducing reliance on steroids – which can present challenges with long-term use,” said Prof Christian Dejaco, Director, Dept of Rheumatology, South Tyrol Health Trust, Bruneck, Italy. “I am encouraged by this positive CHMP opinion for a treatment which could both reduce flares and lower patients’ steroid exposure.”

The positive CHMP opinion is supported by results from the pivotal REPLENISH Phase III trial in which all primary and secondary endpoints were met across both Cosentyx 300mg and 150mg treatment arms, including complete sustained remission and time until patients needed additional treatment through week 52.[2] No new safety signals were identified in PMR patients receiving Cosentyx. 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.[2,9]

“People living with PMR need treatments that provide lasting remission, prevent relapses and are well-tolerated, in order to achieve the best possible long-term outcomes,” said Patrick Horber, M.D., President, International, Novartis. “Cosentyx is the first and only anti-IL-17A shown to provide sustained remission in patients with PMR, and its approval would represent an important step in transforming care for those living with this disease. Today’s positive opinion builds on the well-established impact of Cosentyx in autoimmune disease and could help establish a new standard of care for PMR in Europe.”

Following the CHMP recommendation for approval, the European Commission (EC) is expected to issue a final decision within approximately two months.

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 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)[10-12]. 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.[10-17]

About 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 300mg, Cosentyx 150mg, or placebo, all in combination with a 24-week steroid taper regimen. The primary endpoint of the trial was to assess whether Cosentyx 300mg 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.[18]

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.[3] Relapses are frequent, affecting up to 40% of patients in the first year.[5] Long-term steroid use is the current standard of care and carries significant risks, including osteoporosis and diabetes.[19] Beyond physical complications, PMR substantially impairs quality of life through pain, fatigue, restricted mobility, and fear of relapse.[5,20,21]

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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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," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of

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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 **https://www.novartis.com** and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

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