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PRESS RELEASE

Novartis Cosentyx® PMR data in New England Journal of Medicine showed sustained remission vs placebo in twice as many patients

- *Clinically meaningful, statistically significant efficacy achieved in primary and all secondary endpoints, including reduced steroid use; safety consistent with established Cosentyx profile*[1,2]

- *Polymyalgia rheumatica (PMR) is an inflammatory rheumatic disease primarily affecting people over 50; extended steroid use associated with poor outcomes with limited advanced treatments*[3-7]

- *Data have been submitted for health authority review in US, EU and Japan; additional country filings to follow throughout 2026*

Basel, June 3, 2026 – Novartis presented today new Cosentyx® (secukinumab) data in polymyalgia rheumatica (PMR) demonstrating a statistically significant, clinically meaningful difference in sustained remission rates vs placebo and significant steroid sparing[8]. Published in the *New England Journal of Medicine* and simultaneously presented at the 2026 European Alliance of Associations for Rheumatology (EULAR) Congress, Phase III REPLENISH data showed that the effect of Cosentyx treatment was sustained through week 52 in this investigational use[8].

“PMR is an inflammatory rheumatic disease, characterized by disabling pain and stiffness in shoulders and pelvic girdle. There is an unmet need for a treatment that keeps symptoms under control over time with fewer relapses —while also reducing reliance on steroids,” said Prof Christian Dejaco, Director, Dept of Rheumatology, South Tyrol Health Trust, Bruneck, Italy. “I am encouraged by the REPLENISH trial results which showed that Cosentyx, with its known safety profile, can reduce flares in the longer term while lowering patients’ steroid exposure.”

All primary and secondary endpoints of the REPLENISH trial were met across both Cosentyx 300mg and 150mg treatment arms, including complete sustained remission and time until patients needed additional treatment through week 52[8]. No new safety signals were identified in PMR patients receiving Cosentyx[8].

"The publication of the REPLENISH data in the *New England Journal of Medicine* reflects the importance of these findings for patients with polymyalgia rheumatica (PMR), a disease with very limited advanced treatment options,” said Prof John Stone, MD, MPH, Professor of Medicine, Harvard Medical School, Massachusetts General Hospital, Boston, global principal investigator for the REPLENISH trial and lead author of the New England Journal of Medicine article. “The Phase III results showed a higher proportion of PMR patients achieved sustained remission with Cosentyx and further support IL-17A inhibition as a promising therapeutic approach in this disease.”

“Today’s results demonstrate that Cosentyx fills an unmet need by providing relief and renewed hope for people living with polymyalgia rheumatica (PMR) through improvement in disease control while reducing steroid use,”

said Angelika Jahreis, Global Head, Immunology Development, Novartis. “We look forward to working with health authorities globally to expand the use of Cosentyx supported by the new REPLENISH data.”

Key efficacy results at week 52[8]

Endpoint	Cosentyx 300mg	Cosentyx 150mg	Placebo
Sustained remission	41.2%*	40.6%*	20.4%
Mean adjusted annual cumulative glucocorticoid dose	1604 mg*	1683 mg#	2093 mg

** P-value < 0.001; adjusted for multiple testing*
 # P-value = 0.0015; adjusted for multiple testing

Novartis has submitted Cosentyx for polymyalgia rheumatica for health authority review in the US, EU and Japan. Regulatory submissions in additional countries are expected to follow throughout 2026.

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)[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 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[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[3]. Relapses are frequent, affecting up to 40% of patients in the first year[5], and long-term steroid use, the standard of care, 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[5,19,20].

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 autoimmune diseases. 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," "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 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 regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with 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 contained in this press release 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 **https://www.novartis.com** and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

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