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PRESS RELEASE

Novartis Cosentyx® meets primary and all secondary endpoints in Phase III trial in patients with polymyalgia rheumatica (PMR)

- *Cosentyx® (secukinumab) achieved statistically significant and clinically meaningful sustained remission vs placebo at Week 52[1]*
- *Trial showed reduction in annual cumulative steroid dose vs placebo through Week 52; safety profile consistent with known profile of Cosentyx[1]*
- *Data highlight potential of Cosentyx as novel targeted PMR treatment, second most common inflammatory disease in adults ≥50[2], with limited options available*

Basel, October 22, 2025 – Novartis today announced that Cosentyx® (secukinumab) met the primary endpoint and all secondary endpoints in the Phase III REPLENISH trial[1]. Cosentyx demonstrated statistically significant and clinically meaningful sustained remission vs placebo at Week 52 in adults with polymyalgia rheumatica (PMR)[1]. Data will be presented at an upcoming medical congress and submitted to health authorities in the first half of 2026.

“Polymyalgia rheumatica is an inflammatory rheumatic disease characterized by bilateral pain of the neck, shoulders, or hips, morning stiffness, and fatigue. It tends to flare and significantly impact patients’ quality of life,” said Angelika Jahreis, Global Head, Immunology Development, Novartis. “These results highlight the potential of Cosentyx to help patients achieve and sustain disease remission and reduce corticosteroids, which can lead to significant side effects in this typically elderly patient population. Today’s results represent another breakthrough in transforming care in rheumatology.”

A key secondary endpoint of the REPLENISH trial was adjusted annual cumulative steroid dose through Week 52. Other secondary measures included complete sustained remission at Week 52, and time until patients needed additional treatment[3].

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 is to assess whether secukinumab 300mg sc. 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 include 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[3].

About Cosentyx (secukinumab)
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)[4-6], as well as in pediatric patients with PsO, enthesitis-related arthritis (ERA), and juvenile psoriatic arthritis (JPsA)[7-8].Cosentyx is supported by robust evidence and 10 years of real-world data demonstrating its long-term safety and sustained efficacy[9-14]. Since its launch in 2015, it has been used to treat more than 1.8 million patients worldwide and is now approved in over 100 countries[9].

About polymyalgia rheumatica (PMR)
Polymyalgia rheumatica (PMR) is the second most 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[15], and long-term steroid use, the standard of care, carries significant risks including osteoporosis and diabetes[16]. Beyond physical complications, PMR substantially impairs quality of life through pain, fatigue, restricted mobility, and fear of relapse[17].

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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 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 nearly 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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