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PRESS RELEASE

Novartis receives positive CHMP opinion for Cosentyx® in adolescents aged 12+ with hidradenitis suppurativa (HS)

- *If approved, Cosentyx® (secukinumab) will become the only IL-17A inhibitor for adolescents with moderate to severe HS in Europe*[1,2]
- *HS affects as many as one in 100 people worldwide,*[3] *with more than half developing symptoms during adolescence*[4,5]

Basel, November 13, 2026 – Novartis today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending marketing authorization of Cosentyx® (secukinumab) for adolescents aged 12 years and older with active moderate to severe hidradenitis suppurativa (HS) who have had an inadequate response to conventional systemic HS therapy.[6] If approved by the European Commission (EC), Cosentyx would become the only interleukin-17A (IL-17A) inhibitor approved for adolescent HS in Europe and the first innovative biologic treatment option for this population in nearly a decade, addressing a significant unmet need where treatment options remain limited.[1,2,7,8]

HS is a chronic, systemic, progressive and often painful inflammatory skin disease.[5,9] It causes recurring boil-like abscesses that can burst, creating open wounds, often in the most intimate parts of the body, which may result in irreversible scarring.[5,8-10] More than 50% of cases begin during puberty.[4,5]

"Hidradenitis suppurativa often begins during adolescence, a critical period when the disease can progress to irreversible scarring, yet we currently have limited treatment options for this age group," said Dr. John Ingram, Clinical Professor, Cardiff University School of Medicine, United Kingdom. "This positive CHMP opinion for secukinumab represents an important step toward addressing a meaningful gap in care for young people living with this challenging disease."

The CHMP positive opinion is based on evidence demonstrating that weight-based dosing in adolescents aged 12 years and older provides Cosentyx exposure generally comparable to that observed in adults with HS.[2] This includes efficacy and safety data from adult HS clinical studies, pharmacokinetic modeling extrapolated from adult HS and psoriasis clinical trials, pediatric clinical trial data from other approved Cosentyx indications, and weight-based dosing analyses.[2,11-14] The safety profile of Cosentyx is well-established across several approved adult and pediatric indications.[2,15-17]

"For over a decade, Cosentyx has helped transform outcomes across several immune-mediated diseases, including hidradenitis suppurativa. Adolescents living with moderate to severe HS deserve access to more advanced treatment options," said Patrick Horber, President, International, Novartis. "This positive CHMP opinion brings us closer to that goal in Europe, and we look forward to the European Commission decision in the coming months."

The EC is expected to issue a final decision within approximately two months, following today's CHMP opinion.

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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.[18,19] 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), hidradenitis suppurativa (HS), and polymyalgia rheumatica (PMR).[2,19-21] 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.[2,12-14,19,22,23]

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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References

1. European Medicines Agency. Search results for “hidradenitis suppurativa.” European Medicines Agency. https://www.ema.europa.eu/en/search?search_api_fulltext=polymyalgia%20rheumatica&keywords=allwords&keyword=hidradenitis%20suppurativa%20&f%5B0%5D=is_document%3ADocument&page=0 [Last Accessed: November 2026].
2. 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: November 2026].
3. MedLine Plus. Hidradenitis suppurativa [online]. Available from: https://medlineplus.gov/genetics/condition/hidradenitis-suppurativa/ [Last accessed: November 2026].
4. Molina-Leyva A, Cuenca-Barrales C. Adolescent-onset hidradenitis suppurativa: prevalence, risk factors and disease features. Dermatology. 2019;235(1):45-50. doi:10.1159/000493465
5. Hallock KK, Mizerak MR, Dempsey A, Maczuga S, Kirby JS. Differences between children and adults with hidradenitis suppurativa. JAMA Dermatol. 2021;157(9):1095-1101. doi:10.1001/jamadermatol.2021.2865
6. European Medicines Agency (EMA). Cosentyx, INN-secukinumab: CHMP post-authorisation summary of positive opinion. European Medicines Agency; 2026. Available at: https://www.ema.europa.eu/en/documents/smop/chmp-post-authorisation-summary-positive-opinion-cosentyx-vr-0000340032_en.pdf. [Last Accessed November 13, 2026]
7. AbbVie. AbbVie's HUMIRA® (Adalimumab) Receives CHMP Positive Opinion to Treat Adolescents with Hidradenitis Suppurativa, a Chronic Inflammatory Skin Disease. Available at: https://news.abbvie.com/2016-11-14-AbbVies-HUMIRA-Adalimumab-Receives-CHMP-Positive-Opinion-to-Treat-Adolescents-with-Hidradenitis-Suppurativa-a-Chronic-Inflammatory-Skin-Disease [Last Accessed: November 2026].
8. European Medicines Agency. Biosimilar medicines: Overview. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/biosimilar-medicines-overview [Last Accessed: November 2026].
9. Garg A, Naik HB, Alavi A, et al. Real-World Findings on the Characteristics and Treatment Exposures of Patients with Hidradenitis Suppurativa from US Claims Data. Dermatol Ther (Heidelb). 2023 Feb;13(2):581-594. doi: 10.1007/s13555-022-00872-1.
10. Sabat R, Jemec GBE, Matusiak L, et al. Hidradenitis suppurativa. Nat Rev Dis Primers 2020; 6: 18.
11. Kimball AB, Jemec GBE, Alavi A, et al. Secukinumab in moderate-to-severe hidradenitis suppurativa (SUNSHINE and SUNRISE): week 16 and week 52 results of two identical, multicentre, randomised, placebo-controlled, double-blind phase 3 trials. Lancet 2023; 401: 747-761.
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: November 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: November 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: November 2026].
15. Mease PJ, Kavanaugh A, Reimold A, Tahir H, Rech J, Hall S, Geusens P, Pascale P, Delicha EM, Pricop L, Mpofu S. “Secukinumab Provides Sustained Improvements in the Signs and Symptoms in Psoriatic Arthritis: Final 5-Year Efficacy and Safety Results from a Phase 3 Trial”. ACR/ARHP 2020 Annual Meeting Abstract. Presented in ACR Open Rheumatology (2020); CONCL00511.

16. McInnes IB, Mease PJ, Kivitz AJ, Nash P, Rahman P, Rech J, Conaghan PG, Kirkham B, Navarra S, Belsare AD, Delicha EM, Pricop L, Mpofu S; FUTURE 2 Study Group. “Long-term efficacy and safety of secukinumab in patients with psoriatic arthritis: 5-year (end of study) results from the phase III FUTURE 2 study.” Lancet Rheumatology. 2020; 2(4): e227–e235.
17. Bissonnette R, Luger T, Thaçi D, Toth D, Lacombe A, Xia S, Mazur R, Patekar M, Charef P, Milutinovic M, Leonardi C, Mrowietz U. Secukinumab demonstrates high sustained efficacy and a favourable safety profile in patients with moderate-to-severe psoriasis through 5 years of treatment (SCULPTURE Extension Study). J Eur Acad Dermatol Venereol. 2018 Sep;32(9):1507–1514.
18. Novartis receives European approval for Cosentyx® as first and only IL-17A inhibitor for hidradenitis suppurativa. Available at: https://www.novartis.com/news/media-releases/novartis-receives-european-approval-cosentyx-first-and-only-il-17a-inhibitor-hidradenitis-suppurativa [Last accessed: November 2026].
19. Girolomoni G, Mrowietz U, Paul C. Psoriasis: rationale for targeting interleukin-17. Br J Dermatol. 2012;167(4):717–724.
20. 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: November 2026].
21. Novartis receives European Commission approval for Cosentyx® in polymyalgia rheumatica (PMR). [Press release]. Available at: https://www.novartis.com/news/media-releases/novartis-receives-european-commission-approval-cosentyx-polymyalgia-rheumatica-pmr [Last Accessed: November 2026].
22. 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: November 2026].
23. Cosentyx. Prescribing information. Novartis Pharmaceuticals Corp. Available at: https://www.novartis.com/us-en/sites/novartis_us/files/cosentyx.pdf [Last Accessed: November 2026].

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