

FDA approves Novartis Cosentyx® as the first new biologic treatment option for hidradenitis suppurativa patients in nearly a decade

- *FDA approval based on robust Phase III data in which Cosentyx® (secukinumab) showed rapid relief from symptoms of hidradenitis suppurativa (HS) as early as Week 2¹*
- *As the only IL-17A inhibitor approved for HS, Cosentyx offers a meaningful new treatment option that demonstrated reductions in inflammatory nodules and abscesses, and flares²*
- *HS is a chronic, progressive and often painful disease that may affect 1 in 100 people worldwide^{3,4}*

Basel, October 31, 2023 — Novartis, a global leader in immuno-dermatology and rheumatology, announced today that the US Food and Drug Administration (FDA) has approved Cosentyx® (secukinumab) to treat moderate to severe hidradenitis suppurativa (HS) in adults. Cosentyx is the only FDA-approved fully human biologic that directly inhibits interleukin-17A (IL-17A), a cytokine believed to be involved in the inflammation of HS.²

HS is a chronic, systemic and often painful skin disease that causes recurring boil-like lumps that may burst into open wounds and cause irreversible scarring, often in the most intimate parts of the body.³ It may take people living with HS an average of up to 10 years to get a correct diagnosis, which can result in disease progression and significantly impact their quality of life.^{5,6} Until now, there has been only one biologic approved to treat HS.⁷

“For many patients, the daily impact of HS and the search for symptom relief can last years – which can come with painful, irreversible physical and emotional scarring,” said Alexa B. Kimball, MD, MPH, lead investigator of the SUNSHINE and SUNRISE trials, Professor of Dermatology at Harvard Medical School, President and CEO of Harvard Medical Faculty Physicians at Beth Israel Deaconess Medical Center, Boston. “This approval marks an important milestone for countless patients who have been faced with limited treatment possibilities and who now have a new option.”

“HS is one of the most devastating and exhausting skin diseases. The pain of flares can be debilitating and limits my ability to work or participate in social activities. It can have a major impact on me physically and emotionally, including feelings of anxiety, stress and isolation,” said Donna Atherton, EdD, Founder and Chief Mission Officer, International Association of Hidradenitis Suppurativa Network (IAHSN). “The approval of a new treatment option brings fresh hope to me and the HS community that we may find relief from the burden of the disease.”

The FDA approval was based on analyses from the largest Phase III program in HS to date, SUNSHINE and SUNRISE, in which a higher proportion of patients given Cosentyx 300 mg either every two weeks or every four weeks achieved a Hidradenitis Suppurativa Clinical Response (HiSCR50) compared to placebo.¹ Cosentyx for HS is approved as a 300 mg dose, administered every four weeks, with the option to increase to every two weeks if the patient has an inadequate response.¹

In both the SUNSHINE and SUNRISE studies, which evaluated Cosentyx across 16-week (vs placebo) and 52-week treatment periods, the onset of action of Cosentyx occurred as early as Week 2.¹ Efficacy progressively increased to Week 16 and was observed up to Week 52.² The safety profile of Cosentyx observed in these HS trials was consistent with its known safety profile observed in the plaque psoriasis trials, affirming the differentiated safety profile of Cosentyx.¹

“Cosentyx can offer effective, lasting relief from HS symptoms so that people with HS have a chance to live every day with confidence,” said Victor Bultó, President, Novartis US. “With this sixth indication approval for Cosentyx – along with ongoing studies in numerous other conditions – we are reaffirming our commitment to reimagine medicine for those living with immunological diseases.”

About the SUNSHINE and SUNRISE trials²

The SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) trials comprise the largest Phase III program in hidradenitis suppurativa (HS), with a combined enrollment of more than 1,000 patients. SUNSHINE and SUNRISE are identical, global Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group studies that evaluated the short- (16 weeks) and long-term (up to 52 weeks) efficacy, safety and tolerability of two dose regimens of Cosentyx in adults with moderate to severe HS. A Hidradenitis Suppurativa Clinical Response (HiSCR50), the primary endpoint in the two pivotal trials, is defined as at least a 50% decrease in abscess and inflammatory nodule (AN) count with no increase in the number of abscesses and/or draining tunnels. Secondary endpoints included a decrease in abscess and inflammatory nodules by at least 50% (AN50), the proportion of patients experiencing a flare, and the proportion of patients with a skin pain numeric rating scale 30 response up to 16 weeks of treatment.²

Results from the US Food and Drug Administration (FDA)-requested analyses at Week 16 showed that a significantly higher proportion of patients achieved HiSCR50 when treated with Cosentyx 300 mg dosed every two weeks (after standard weekly loading doses), compared with placebo in both the SUNSHINE and SUNRISE trials (44.5% vs 29.4% [$*P<0.05$] and 38.3% vs 26.1% [$*P<0.05$], respectively).¹ A greater proportion of patients randomized to Cosentyx 300 mg dosed every four weeks (after standard weekly loading doses) achieved HiSCR50 compared with placebo in both SUNSHINE (41.3% vs 29.4%) and SUNRISE (42.5% vs 26.1% [$*P<0.05$]) trials.¹

An exploratory analysis assessed the long-term effects of Cosentyx for each of the primary and secondary endpoints for up to 52 weeks. HiSCR values observed at Week 16 following either dose regimen of Cosentyx were improved over time to Week 52 (SUNSHINE: SECQ2W [56.4%]; SECQ4W [56.3%]; SUNRISE: SECQ2W [65.0%]; SECQ4W [62.2%]), with rapid improvements seen in patients who switched from placebo at Week 16.⁸

*Statistically significant versus placebo based on the pre-defined hierarchy (from the pre-specified primary statistical analysis) with overall alpha = 0.05 (two-sided).

About Cosentyx® (secukinumab)

Cosentyx is the first and only fully human biologic that specifically targets and blocks interleukin-17A (IL-17A), an important cytokine involved in the inflammation of psoriatic arthritis (PsA), moderate to severe plaque psoriasis, ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).^{9,10} Cosentyx is a proven medicine and has been studied clinically for more than 14 years. The medicine is backed by robust evidence, including 8 years of real-world data in adults and 5 years of long-term safety and efficacy across moderate to severe plaque psoriasis, PsA and AS.¹¹⁻¹⁷ These data strengthen the position of Cosentyx as a treatment across AS, nr-axSpA, PsA, moderate to severe plaque psoriasis (adult and pediatric) and two subtypes of juvenile idiopathic arthritis (JIA), enthesitis-related arthritis and juvenile psoriatic arthritis.¹ More than 1 million patients have been treated with Cosentyx worldwide since its launch in 2015.¹⁸ Cosentyx is approved in more than 100 countries, most recently gaining approval for JIA and HS in the US and Europe.^{19,20}

Disclaimer

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About Novartis

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References

1. Cosentyx Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corp; October 2023.
2. Kimball AB, Jemec GBE, Alavi A, et al. Secukinumab in moderate to severe hidradenitis suppurativa (SUNSHINE and SUNRISE): week 16 and 52 results of two identical, double-blind, placebo-controlled, phase 3 randomised trials. *Lancet*. 2023; published online Feb 3. Available at: [https://doi.org/10.1016/S0140-6736\(23\)00022-3](https://doi.org/10.1016/S0140-6736(23)00022-3) [Last accessed: February 2023].
3. MedLine Plus. Hidradenitis suppurativa [online]. Available at: <https://medlineplus.gov/genetics/condition/hidradenitis-suppurativa/> [Last accessed: March 2022].
4. Sabat R, Jemec GBE, Matusiak L, et al. Hidradenitis suppurativa. *Nat Rev Dis Primers* 2020;6:18. doi: 10.1038/s41572-020-0149-1
5. Kokolakis G, Wolk K, Schneider-Burrus S, et al. Delayed Diagnosis of Hidradenitis Suppurativa and Its Effect on Patients and Healthcare System. *Dermatology*. 2020;236:421-430.
6. Kimball AB, Okun MM, Williams DA, et al. Two phase 3 trials of adalimumab for hidradenitis suppurativa. *N Engl J Med*. 2016;375:422-434.
7. Martora F, Megna M, Battista T, et al. Adalimumab, Ustekinumab, and Secukinumab in the Management of Hidradenitis Suppurativa: A Review of the Real-Life Experience. *Clin Cosmet Invest Dermatol*. 2023;16:135-148. Published 2023 Jan 19. doi:10.2147/CCID.S391356 4.
8. Kimball AB, Jemec GBE, Alavi A, et al. Efficacy and Safety of Secukinumab in Patients with Moderate to Severe Hidradenitis Suppurativa from the Phase 3 SUNSHINE and SUNRISE Trials. Poster presented at American Academy of Dermatology (AAD) 2023 Annual Meeting; March 17-21, 2023, New Orleans, LA.
9. Girolomoni G, Mrowietz U and Paul C. Psoriasis: rationale for targeting interleukin-17. *Br J Dermatol*. 2012;167:717-24.
10. McGonagle DG, McInnes IB, Kirkham BW, et al. The role of IL-17A in axial spondyloarthritis and psoriatic arthritis: recent advances and controversies. *Annals Rheum Dis*. 2019;78:1167-1178.
11. Baraliakos X, Braun J, Deodhar A, et al. Long-term efficacy and safety of secukinumab 150 mg in ankylosing spondylitis: 5-year results from the phase III MEASURE 1 extension study. *RMD Open*. 2019;5:e001005.
12. Bissonnette R, Luger T, Thaçi D, et al. 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;32:1507-1514.
13. Mease PJ, Kavanaugh A, Reimold A, et al. Secukinumab Provides Sustained Improvements in the Signs and Symptoms of Psoriatic Arthritis: Final 5-year Results from the Phase 3 FUTURE 1 Study. *ACR Open Rheumatol*. 2020;2:18-25.
14. Data on file. CAIN457F2310 (MEASURE 1 and 2): Pooled Safety Data. Novartis Pharmaceuticals Corp; July 23, 2018.
15. Data on file. CAIN457F2310 and CAIN457F2305 summary of 5-year clinical safety in (ankylosing spondylitis). Novartis Pharmaceuticals Corp; May 2019.
16. Data on file. CAIN457F2312 Data Analysis Report. Novartis Pharmaceuticals Corp; November 2008.

17. McInnes IB, Mease PJ, Kirkham B, et al. Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet* 2015;386:1137-46.
18. Data on file. COSENTYX Access. Novartis Pharmaceuticals Corp; January 2023.
19. Novartis AG. 2021. 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: February 2023].
20. 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: July 2023].

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