Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

https://www.novartis.com
https://twitter.com/novartisnews

MEDIA UPDATE

Novartis receives European approval for Cosentyx® as first and only IL-17A inhibitor for hidradenitis suppurativa

- *Cosentyx® (secukinumab) is the first new biologic treatment for hidradenitis suppurativa (HS) in nearly a decade, offering clinically meaningful results across the most debilitating symptoms[1,2]*

- *European approval is based on robust Phase III data showing Cosentyx provided rapid symptom relief from as early as Week 4, with response rates continuing to improve up to 1 year[1,3-5]*

- *Cosentyx has a known safety profile, established across six approved indications and 8 years of real-world use in more than 1 million patients[1,6,7]*

- *HS is a chronic inflammatory skin disease resulting in painful and potentially disfiguring abscesses[2]; around 200,000 people in Europe currently live with moderate to severe stages of the condition[8]*

Basel, June 1, 2023 — Novartis announced today that the European Commission (EC) has approved Cosentyx® (secukinumab) for use in adults with active moderate to severe hidradenitis suppurativa (HS) and an inadequate response to conventional systemic HS therapy[7].

“With only one currently approved treatment option, I see HS patients with a tremendous need for alternatives that reduce the disabling physical symptoms of HS, improve the emotional burden and help partially avoid invasive surgery, if treating early,” said Professor Christos C. Zouboulis, President of the European Hidradenitis Suppurativa Foundation, Director of the Departments of Dermatology, Venereology, Allergology and Immunology, Städtisches Klinikum Dessau, and Founding Professor of Dermatology and Venereology at the Brandenburg Medical School, Germany. “This expanded approval offers physicians an additional effective and, for dermatologists, familiar treatment choice that we can feel confident in prescribing for this complex and challenging disease.”

“Since its first approval in 2015, Cosentyx has been used to treat more than 1 million people worldwide. We are pleased to bring Cosentyx as a much needed and trusted treatment option that brings rapid and sustained symptom relief to HS patients,” said Haseeb Ahmad, President Europe, Novartis. “With established market access and patient support programs, Novartis is in a strong position to support fast and widespread access to Cosentyx. This

milestone approval is a major step forward in our ambition to deliver quality medicines that alleviate major unmet medical needs."

A regulatory decision from the US Food and Drug Administration is expected later this year.

About the SUNSHINE and SUNRISE trials[1,9,10]
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 in 40 countries. SUNSHINE and SUNRISE evaluated the short- (16 weeks) and long-term (up to 52 weeks) efficacy, safety and tolerability of two dose regimens of Cosentyx® (secukinumab) in adults with moderate to severe HS. Results published in *The Lancet* showed that treatment response rates in patients randomized to Cosentyx continued to improve beyond the primary endpoint analysis at Week 16 to more than 55% of patients achieving a Hidradenitis Suppurativa Clinical Response (HiSCR), the primary endpoint, at Week 52. The safety profile was consistent with that of Cosentyx in its other indications.

About Cosentyx® (secukinumab)
Cosentyx is the first and only fully human biologic that directly inhibits interleukin-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)[7,11]. Cosentyx is a proven medicine and has been studied clinically for more than 14 years. The medicine is backed by robust evidence, including 5 years of clinical data in adults supporting long-term safety and efficacy across moderate to severe plaque psoriasis, PsA and AS[12-18]. 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[7]. More than 1 million patients have been treated with Cosentyx worldwide since its launch in 2015[6]. Cosentyx is approved in more than 100 countries[19], most recently gaining approval for JIA in the US and Europe[20,21]. We are continuing to explore the potential of Cosentyx in other indications in areas of high unmet need, including lupus nephritis and giant cell arteritis in rheumatology, where Phase III trials are in progress, as well as polymyalgia rheumatica and rotator cuff tendinopathy.

About hidradenitis suppurativa (HS)
HS is a painful, chronic and progressive inflammatory skin disease[2]. It causes recurring boil-like abscesses that can burst, creating open wounds, often in the most intimate parts of the body, resulting in irreversible scarring[2,22]. It can take up to 10 years on average to get a diagnosis, even though HS affects approximately 1 in 100 people globally[22,23]. There is currently only one approved biologic treatment and around 50% of patients treated can lose response[24]. In advanced cases, healthcare professionals often consider surgery to remove abscesses, an invasive procedure that frequently results in additional scarring[2]. HS impacts patients' quality of life more than any other skin disease, and people living with HS often experience comorbidities such as obesity, diabetes, arthritis and depression[2,25,26].

Disclaimer
This media update 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 media update, 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 media update 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 such as COVID-19; 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 media update as of this date and does not undertake any obligation to update any forward-looking statements contained in this media update as a result of new information, future events or otherwise.

About Novartis

Novartis is reimagining medicine to improve and extend people's lives. We deliver high-value medicines that alleviate society's greatest disease burdens through technology leadership in R&D and novel access approaches. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. About 103,000 people of more than 140 nationalities work together to bring Novartis products to nearly 800 million people around the world. Find out more at **https://www.novartis.com**.

Novartis is on Twitter. Sign up to follow @Novartis at **https://twitter.com/novartisnews**
For Novartis multimedia content, please visit **https://www.novartis.com/news/media-library**
For questions about the site or required registration, please contact media.relations@novartis.com

References

1. 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.
2. Sabat R, Jemec GBE, Matusiak L, et al. Hidradenitis suppurativa. Nat Rev Dis Primers 2020; 6: 18.
3. Data on file. NCT03713619 and NCT03713632 (SUNSHINE and SUNRISE): Pooled Data Tables. Novartis Pharmaceuticals Corp; 2022.
4. Data on file. NCT03713619 and NCT03713632 (SUNSHINE and SUNRISE): Summary of Clinical Efficacy. Novartis Pharmaceuticals Corp; 2022.
5. Data on file. NCT03713619 and NCT03713632 (SUNSHINE and SUNRISE): Clinical Study Program post-hoc analysis of skin pain NRS severity. Novartis Pharmaceuticals Corp; 2022.
6. Data on file. COSENTYX Access. Novartis Pharmaceuticals Corp; January 2023.
7. 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: May 2023].
8. Data on file. Novartis Pharmaceuticals Corp; March 2023.
9. ClinicalTrials.gov. Study of Efficacy and Safety of Two Secukinumab Dose Regimens in Subjects With Moderate to Severe Hidradenitis Suppurativa (HS) (SUNRISE). NCT03713632. Available from: https://clinicaltrials.gov/ct2/show/NCT03713632 [Last accessed: May 2023].
10. ClinicalTrials.gov. This is a Study of Efficacy and Safety of Two Secukinumab Dose Regimens in Subjects With Moderate to Severe Hidradenitis Suppurativa (HS). (SUNSHINE). NCT03713619. Available from: https://clinicaltrials.gov/ct2/show/NCT03713619 [Last accessed: May 2023].
11. Girolomoni G, Mrowietz U and Paul C. Psoriasis: rationale for targeting interleukin-17. Br J Dermatol 2012; 167: 717-724.
12. 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.
13. 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.

14. 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.
15. Data on file. CAIN457F2310 (MEASURE 1 and 2): Pooled Safety Data. Novartis Pharmaceuticals Corp; July 23, 2018.
16. Data on file. CAIN457F2310 and CAIN457F2305 summary of 5-year clinical safety in (ankylosing spondylitis). Novartis Pharmaceuticals Corp; May 2019.
17. Data on file. CAIN457F2312 (FUTURE 2): 5 year-interim report. Novartis Pharmaceuticals Corp; May 2019.
18. 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: 1137-1146.
19. Data on file. COSENTYX Approvals. Novartis Pharmaceuticals Corp; March 2023.
20. 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: May 2023].
21. Novartis AG. 2022. Novartis Cosentyx® (secukinumab) 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: May 2023].
22. MedLine Plus. Hidradenitis suppurativa [online]. Available at: https://medlineplus.gov/genetics/condition/hidradenitis-suppurativa/ [Last accessed: May 2023].
23. 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.
24. 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.
25. Mac Mahon J, Kirthi S, Byrne N, et al. An Update on Health-Related Quality of Life and Patient-Reported Outcomes in Hidradenitis Suppurativa. Patient Relat Outcome Meas 2020; 11: 21-26.
26. Trinidad M-V, Manuel S-D, Antonio M-L, et al. Quality of Life in Patients with Skin Disease and Their Cohabitants. In: M. Jasneth, A. Sage and C. Medhane, eds. Health-Related Quality of Life Rijeka: IntechOpen; 2021: Ch. 5.

# # #

Novartis Media Relations
E-mail: media.relations@novartis.com

Central		North America	
Richard Jarvis	+41 79 584 2326	Julie Masow	+1 862 579 8456
Anja von Treskow	+41 79 392 9697	Michael Meo	+1 862 274 5414
Anna Schäfers	+41 79 801 7267	Mary Carmichael	+1 862 200 8344
		Marlena Abdinoor	+1 617 335 9525

Switzerland
Satoshi Sugimoto +41 79 619 2035

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Sloan Simpson	+1 862 345 4440
Nicole Zinsli-Somm	+41 61 324 3809	Parag Mahanti	+1 973 876 4912
Isabella Zinck	+41 61 324 7188		