Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

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

MEDIA & INVESTOR RELEASE

Novartis Cosentyx® shows clinically meaningful symptom improvements in patients with hidradenitis suppurativa in pivotal Phase III trials

- *Results from two parallel trials show Cosentyx® (secukinumab) demonstrated superior efficacy vs placebo with statistically significant improvement in hidradenitis suppurativa (HS) signs and symptoms*[1]

- *Safety results were consistent with the well-established Cosentyx safety profile*

- *HS is a chronic, inflammatory skin condition affecting up to one in 100 people worldwide*[2]*, resulting in painful, potentially disfiguring lesions, which leaves feelings of stigmatization and can severely impact quality of life*[3,4]

- *Data from SUNSHINE and SUNRISE trials were submitted as part of regulatory applications to health authorities in Europe; plan to submit in the US by year end*

Basel, September 10, 2022 — Novartis announced the results from two pivotal, Phase III studies (SUNSHINE and SUNRISE), in which Cosentyx® (secukinumab) demonstrated rapid and sustained relief from the common clinical signs and symptoms of moderate-to-severe hidradenitis suppurativa (HS) with a favorable safety profile[5,6]. The data were presented as a late-breaking abstract at the 31st European Academy of Dermatology and Venereology (EADV) Congress[1].

“Hidradenitis suppurativa can cause intense pain, disability and anxiety, impacting many aspects of daily living. However, there are only limited treatment options available that can make a difference to people living with this debilitating disease,” said Dr. Alexa B. Kimball, lead investigator of the trials, investigator at Beth Israel Deaconess Medical Center, and Professor of Dermatology, Harvard Medical School. “These efficacy and safety findings are promising for people living with HS, who are in urgent need of new treatment options.”

These Phase III data have been submitted to regulatory authorities in Europe and will be submitted to regulatory authorities in the United States this year, with the goal of bringing Cosentyx as a new treatment option to patients living with HS as soon as possible. Novartis also plans to share the long-term results from the trials in 2023. Available data support the sustained efficacy over continuous treatment up to 52 weeks in patients with HS[7].

“We are excited to share these promising results showing the benefit of Cosentyx as a treatment that provides relief from common signs and symptoms, pain and flares for people living with HS, with a favorable safety profile. We hope to offer Cosentyx as a potential new treatment option as soon as possible to support this underserved patient community, as part

of our ambition to expand Cosentyx to 10 indications," said Todd Fox, Global Head of Medical Affairs Immunology, Novartis. "Beyond Cosentyx, we are also committed to advancing research in HS and are currently exploring a number of treatments with various mechanisms of action with hopes to further address the ongoing unmet needs of people living with this disease."

The trials assessed two Cosentyx dose regimens across 16-week (vs placebo) and 52-week treatment periods. Results showed a significantly higher proportion of patients achieved a Hidradenitis Suppurativa Clinical Response (HiSCR) when treated with Cosentyx 300 mg, dosed every two weeks (after standard weekly loading doses), compared with placebo at Week 16 in both the SUNSHINE and SUNRISE trials (45.0% vs 33.7% [P=.0070] and 42.3% vs 31.2% [P=0.0149], respectively)[1]. Cosentyx 300 mg dosed every four weeks (after standard weekly loading doses) was superior to placebo for achieving HiSCR in the SUNRISE study (46.1% vs 31.2% [P=0.0022]), though did not meet statistical significance in the SUNSHINE study (41.8% vs 33.7% [P=0.0418])[5,6]. HiSCR is defined as at least a 50% decrease in abscess and inflammatory nodule count with no increase in the number of abscesses and/or draining tunnels[5,6]. The safety profile was consistent with that of Cosentyx in existing indications, and no new safety signals were observed in either dosing group[1].

A key secondary endpoint was skin pain, as measured by the patient's global assessment of skin pain Numeric Rating Scale (NRS30). In data pooled from the two studies, the 300 mg dose of Cosentyx given every two weeks proved statistically superior to placebo in reducing skin pain, the most bothersome symptom of HS[1,8]. Further details on the primary and secondary endpoints are available on the Novartis website: https://www.novartis.com/healthcare-professionals/medical-congresses-and-events/abstract-summaries-eadv.

Since its initial approval in 2015, Cosentyx has helped more than 700,000 patients worldwide across five approved immune-mediated diseases, with the goal of preventing disease progression across even more immunological conditions in the future while demonstrating sustained treatment efficacy and safety[9-20].

About the SUNSHINE and SUNRISE trials

The SUNSHINE and SUNRISE trials comprise the largest Phase III program in hidradenitis suppurativa (HS), having enrolled more than 1,000 patients in 33 countries[5,6]. SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) 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. SUNSHINE included 541 patients, and SUNRISE included 543 patients. Patients in each study were randomized to one of three experimental arms: Cosentyx 300 mg every two weeks after five weekly loading doses; Cosentyx 300 mg every four weeks after five weekly loading doses; placebo dose every two weeks after five weekly placebo doses. The primary endpoint of both trials assessed achievement of HS Clinical Response (HiSCR) after 16 weeks of treatment. Key secondary endpoints included the percentage change from baseline in abscess and inflammatory nodule (AN) count at Week 16, proportion of patients experiencing a flare over 16 weeks, and proportion of patients with Numeric Rating Scale 30 (skin pain) response (reported as pooled data from both trials) at Week 16.

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)[16,21]. Cosentyx is a proven medicine and has been studied clinically for more than 14 years. The medicine is backed by robust evidence, including five years of clinical data in adults supporting long-term safety and efficacy across moderate to severe plaque psoriasis, PsA and AS[9-15,22]. 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 (ERA) and juvenile psoriatic arthritis (JPsA). More than 700,000 patients have been treated with Cosentyx worldwide since launch in 2015[16,19,20]. Cosentyx is approved in more than 100 countries, most recently gaining approval for JIA in the United States and Europe.

About hidradenitis suppurativa (HS)
HS is a chronic, inflammatory, debilitating skin condition with systemic comorbidities that has a profoundly negative effect on a patient's quality of life and mental health[2-4]. It is characterized by recurrent lumps or nodules under the skin that become inflamed and painful, breaking open to cause abscesses and sores[2,23]. The chronic debilitating nature of HS makes it one of the most distressing dermatological conditions, with a considerable psychological burden on sufferers[3]. Once considered a rare condition, it is now thought that as many as one in 100 people are affected by HS[2]. There is no cure for HS and current HS treatment regimens are limited, often inadequate and can require a surgical approach[24,25]. Often, they cannot be taken for an extended time, or only provide temporary and moderate relief[24,25]. It takes on average seven years to get an HS diagnosis after the first onset of symptoms[26].

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," "seek," "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 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 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 reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 108,000 people of more than 140 nationalities work at Novartis 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, Alavi A, Jemec GBE, et al. Secukinumab in moderate to severe hidradenitis suppurativa: Primary endpoint analysis from the SUNSHINE and SUNRISE Phase 3 trials. LB-3549. Presented at the 31st European Academy of Dermatology and Venereology (EADV) Congress; September 7–10, 2022; Milan, Italy.
2. MedLine Plus. Hidradenitis suppurativa [online]. Available from: https://medlineplus.gov/genetics/condition/hidradenitis-suppurativa/ [Last accessed: September 2022].
3. 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.
4. Sabat R, Jemec GBE, Matusiak L, et al. Hidradenitis suppurativa. Nat Rev Dis Primers. 2020;6:18.
5. 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: September 2022].
6. 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: September 2022].
7. Novartis Data on file. SUNSHINE and SUNRISE trials. [Last accessed: September 2022].
8. Montero-Vilchez T, Diaz-Calvillo P, Rodriguez-Pozo JA, et al. The Burden of Hidradenitis Suppurativa Signs and Symptoms in Quality of Life: Systematic Review and Meta-Analysis. Int J Environ Res Public Health. 2021;18.
9. 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.
10. 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.
11. 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.
12. 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.
13. Data on file. CAIN457F2310 (MEASURE 1 and 2): Pooled Safety Data. Novartis Pharmaceuticals Corp; July 23, 2018.
14. Data on file. CAIN457F2310 and CAIN457F2305 summary of 5-year clinical safety in (ankylosing spondylitis). Novartis Pharmaceuticals Corp; May 2019.
15. Data on file. CAIN457F2312 Data Analysis Report. Novartis Pharmaceuticals Corp; November 2008.
16. Novartis Europharm Limited. Cosentyx® (secukinumab): Summary of Product Characteristics. Available from: https://www.ema.europa.eu/en/documents/product-information/cosentyx-epar-product-information_en.pdf [Last accessed: September 2022].
17. Ruperto N, Foeldvari I, Alexeeva E, et al. Efficacy and Safety of Secukinumab in Enthesitis-related Arthritis and Juvenile Psoriatic Arthritis: Primary Results from a Randomised, Double-blind, Placebo-controlled, Treatment Withdrawal, Phase 3 Study (JUNIPERA). Presented as a late-breaking abstract at European Alliance of Associations For Rheumatology (EULAR) Virtual Congress; June 2-5, 2021. Abstract LB0004.
18. Brunner H, Foeldvari I, Alexeeva E, et al. Secukinumab Treatment In Children And Adolescents with Enthesitis-Related Arthritis And Juvenile Psoriatic Arthritis: Efficacy And Safety Results From A Phase 3 Study. Presented at the American College of Rheumatology (ACR) Convergence; October 28-30, 2021. Abstract 1424.
19. Data on file. COSENTYX Access. Novartis Pharmaceuticals Corp; December 2021.
20. Data on file. AIN457A2102 Clinical Study Report. Novartis Pharmaceuticals Corp; December 2008.
21. Girolomoni G, Mrowietz U and Paul C. Psoriasis: rationale for targeting interleukin-17. Br J Dermatol. 2012;167:717-24.

22. McInnes IB, Behrens F, Mease PJ, et al. Secukinumab versus adalimumab for treatment of active psoriatic arthritis (EXCEED): a double-blind, parallel-group, randomised, active-controlled, phase 3b trial. Lancet. 2020;395:1496-1505.
23. National Institute of Health (NIH) Genetic and Rare Diseases Information Center (GARD). Hidradenitis suppurativa [online]. Available from: https://rarediseases.info.nih.gov/diseases/6658/hidradenitis-suppurativa#ref_15130 [Last accessed: September 2022].
24. Vinkel C and Thomsen SF. Hidradenitis Suppurativa: Causes, Features, and Current Treatments. J Clin Aesthet Dermatol. 2018;11:17-23.
25. Gill L, Williams M and Hamzavi I. Update on hidradenitis suppurativa: connecting the tracts. F1000Prime Rep. 2014;6:112.
26. Saunte DM, Boer J, Stratigos A, et al. Diagnostic delay in hidradenitis suppurativa is a global problem. Br J Dermatol. 2015;173:1546-9.

# # #

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

Michael Meo
Novartis US External Communications
+1 862 274 5414 (direct)
michael.meo@novartis.com

Chandler Wright
Novartis Pharma Communications
+1 470 660 2365 (direct)
chandler.wright@novartis.com

Julie Masow
Novartis US External Communications
+1 862 579 8456
julie.masow@novartis.com

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	Alina Levchuk	+1 862 778 3372
Isabella Zinck	+41 61 324 7188	Parag Mahanti	+1 973 876 4912