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 worldwide3,4 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 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; 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 a focused 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 250 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. References Cosentyx Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corp; October 2023.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 [Last accessed: February 2023].MedLine Plus. Hidradenitis suppurativa [online]. 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Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/cosentyx-epar-product-information_en.pdf [Last accessed: July 2023]. # # # 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 Anna Schäfers +41 79 392 9697 +41 79 801 7267 Michael Meo Marlena Abdinoor +1 862 274 5414 +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