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MEDIA & INVESTOR RELEASE

Novartis Cosentyx® gains fourth indication in EU with first-in-class approval in axial spondyloarthritis spectrum

- *Cosentyx® is the first fully-human IL-17A inhibitor indicated for patients in Europe with non-radiographic axial spondyloarthritis (nr-axSpA), which forms part of the axial spondyloarthritis (axSpA) disease spectrum*
- *There are approximately 1.7 million patients with nr-axSpA in the top five EU countries and US*[1]
- *Cosentyx is also approved for the treatment of moderate-to-severe plaque psoriasis (PsO), psoriatic arthritis (PsA) and ankylosing spondylitis (AS)*[2-4]
- *This approval underlines Cosentyx leadership in rheumatology and immuno-dermatology, with plans to expand to 10 indications over the next 10 years*

Basel, April 29, 2020 — Novartis, a leader in rheumatology and immuno-dermatology, today announced the European Commission (EC) has approved Cosentyx® (secukinumab) for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA).

“This approval of Cosentyx for non-radiographic axial spondyloarthritis means clinicians across Europe now have an effective new treatment option to help patients gain relief from the burden of this painful, debilitating disease and achieve a better quality of life both at home and at work,” said Atul Deodhar, MD, Professor of Medicine and Medical Director of Rheumatology Clinics at Oregon Health & Science University, USA, and an investigator in the PREVENT clinical trial.

The approval is based on data from the Phase III PREVENT study, in which Cosentyx met the primary endpoint. In the study, 41.5% of nr-axSpA patients treated with Cosentyx 150 mg showing a significant and clinically meaningful reduction in disease activity versus placebo (41.5% vs 29.2%: $p<0.05$), as measured by at least a 40% improvement in ASAS40 at week 16[5], with improvements continued through week 52. Statistically significant improvements in secondary endpoints were also demonstrated, including pain, disease burden and health-related quality of life[5]. PREVENT is the largest ever study of a biologic in patients with nr-axSpA[5].

“Whether a patient has nr-axSpA or AS, the condition has a significant impact on their everyday life. We therefore welcome the news that Cosentyx has gained approval for the treatment of this form of axial spondyloarthritis because it enables patients to realize relief from their symptoms earlier in the spectrum of disease,” said Eric Hughes, Global Development Unit Head, Immunology, Hepatology & Dermatology at Novartis. “This is a firm

demonstration of our commitment to reimagine medicine for patients and a step forward in our plans to expand Cosentyx across ten indications over the next ten years."

Novartis is working closely with all stakeholders to ensure that eligible European patients can start benefitting from Cosentyx as quickly as possible. Novartis has also submitted Cosentyx for review by the US Food and Drug Administration (FDA) and the Japan Pharmaceuticals and Medical Devices Agency (PMDA) for the treatment of adults with nr-axSpA.

About axSpA
AxSpA is a spectrum of long-term inflammatory disease characterized by chronic inflammatory back pain[6]. The axSpA spectrum includes AS, in which joint damage is generally visible on x-ray, and nr-axSpA, in which joint damage is not visible on x-ray[6,7]. Both parts of the disease spectrum have a comparable symptom burden, including nocturnal waking caused by pain, spinal pain, morning stiffness, fatigue and functional disability[8]. If left untreated, axSpA impairs activity, leads to lost work time and has a significant impact on quality of life, including family relationships[8].

About Cosentyx
Cosentyx is the first and only fully-human biologic that directly inhibits IL-17A, a cornerstone cytokine involved in the inflammation and development of PsO, PsA and AS[9-12].

Cosentyx is backed by robust clinical evidence, including five-year data across three indications of PsO, PsA and AS, as well as data from real world evidence[3-5]. These data strengthen the unique position of Cosentyx as a rapid and long-lasting comprehensive treatment across axSpA, PsA and psoriatic disease, with more than 300,000 patients treated worldwide with Cosentyx since launch[13].

About PREVENT
PREVENT is an ongoing two-year randomized, double-blind, placebo-controlled Phase III study (with a two-year extension phase) to investigate the efficacy and safety of Cosentyx, in patients with active nr-axSpA. The study enrolled 555 male and female adult patients with active nr-axSpA (with onset before 45 years of age, spinal pain rated as >=40/100 on a visual analog scale (VAS) and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) >=4) and who had been taking at least two different non-steroidal anti-inflammatory drugs (NSAIDs) at the highest dose up to 4 weeks prior to study start. Patients may have previously taken a TNF inhibitor (not more than one) but had an inadequate response. Of the 555 patients enrolled in the study, 501 (90.3%) were biologic naïve. Patients were allocated to one of three treatment groups: Cosentyx 150 mg subcutaneously with loading dose (induction: 150 mg secukinumab subcutaneously weekly for 4 weeks, then maintenance with 150 mg secukinumab monthly); Cosentyx 150 mg no loading dose (150 mg secukinumab subcutaneously monthly), or placebo (induction of subcutaneously weekly for 4 weeks, followed by maintenance of once-monthly)[14].

The primary endpoints are the proportion of patients achieving an ASAS40 response with Cosentyx 150 mg at Weeks 16 and 52 in TNF-naive patients. Secondary endpoints include among others change in BASDAI over time and change in the Ankylosing Spondylitis Disease Activity Score with CRP (ASDAS-CRP)[14].

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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 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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References

1. DRG Epidemiology Database - Axial Spondyloarthritis: Disease Landscape & Forecast. August 2019 [Internet]. Available from: https://decisionresourcesgroup.com/report/716950-biopharma-axial-spondyloarthritis-landscape-forecast/. [Last accessed: April 2020].
2. Baraliakos X et al. Long-term Evaluation of Secukinumab in Ankylosing Spondylitis: 5 Year Efficacy and Safety Results from a Phase 3 Trial. Presented as a late-breaking abstract at the American College of Rheumatology Annual Meeting, 2018.
3. Bissonnette R, et al. Secukinumab demonstrates high sustained efficacy and a favorable safety profile through 5 years of treatment in moderate to severe psoriasis. J Eur Acad Dermatol Venereol 2018;32:1507–1514.
4. Mease PJ, 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(1):18–25.
5. Deodhar A, et al. Secukinumab 150 mg Significantly Improved Signs and Symptoms of Non-radiographic Axial Spondyloarthritis: Results from a Phase 3 Double-blind, Randomized, Placebo-controlled Study. Abstract presented at: annual meeting of the American College of Rheumatology / Association of Rheumatology Health Professionals; 2019 Nov 8-13; Atlanta, GA.
6. Strand V, et al. Patient Burden of Axial Spondyloarthritis. *J Clin Rheumatol.* 2017 Oct; 23(7): 383–391.
7. Rudwaleit M, van der Heijde D, Landewé R, et al. The development of Assessment of SpondyloArthritis International Society classification criteria for axial spondyloarthritis (part II): validation and final selection. Ann Rheum Dis. 2009;68(6):777-783.
8. Mease PJ, van der Heijde D, Karki C, et al. Characterization of patients with ankylosing spondylitis and non-radiographic axial spondyloarthritis in the US-based Corrona Registry. Arthritis Care Res (Hoboken). 2018;70(11):1661-1670.
9. Novartis Europharm Limited. Cosentyx (secukinumab): Summary of Product Characteristics. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003729/human_med_001832.jsp&mid=WC0b01ac058001d124 [Last accessed: April 2020].

10. Girolomoni G, et al. Psoriasis: rationale for targeting interleukin-17. *Br J Dermatol* 2012;167:717–724.
11. Sieper J, et al. The IL-23–IL-17 pathway as a therapeutic target in axial spondyloarthritis. Nat Rev Rheumatol 2019; 15:747–757.
12. Brembilla NC, Senra L, Boehncke W-H. The IL-17 Family of Cytokines in Psoriasis: IL-17A and Beyond. Front. Immunol. 2018;9:1682. doi: 10.3389/fimmu.2018.01682
13. Data on file. COSENTYX Access. Novartis Pharmaceuticals Corp; May 2019
14. ClinicalTrials.gov. Study of Efficacy and Safety of Secukinumab in Patients With Non-radiographic Axial Spondyloarthritis (PREVENT). Available from: https://clinicaltrials.gov/ct2/show/NCT02696031 [Last accessed: April 2020].

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