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Novartis Cosentyx® gains positive CHMP opinion for new indication in the axial spondyloarthritis spectrum

- *EMA CHMP positive opinion in non-radiographic axial spondyloarthritis (nr-axSpA) paves way for fourth indication in Europe, and is based on Phase III PREVENT data*[1]
- *If approved, Cosentyx would become the first fully-human IL-17A inhibitor indicated for patients in Europe with nr-axSpA*
- *There are approximately 1.7 million patients with nr-axSpA in the top five EU countries and US, which forms part of the axial spondyloarthritis (axSpA) disease spectrum*[2]
- *Cosentyx is backed by five years of clinical data supporting long-term safety and efficacy across ankylosing spondylitis (AS), psoriatic arthritis (PsA) and moderate-to-severe plaque psoriasis (PsO)*[3-6]

Basel, March 27, 2020 — Novartis, a leader in rheumatology and immuno-dermatology, today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for Cosentyx® (secukinumab) for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA).

“Non-radiographic axial spondyloarthritis is part of the axSpA spectrum and is a painful and debilitating disease for which there are limited treatment options available,” said Eric Hughes, Global Development Unit Head, Immunology, Hepatology & Dermatology at Novartis. “This positive opinion marks another step forward in our commitment to reimagine medicine in axSpA and help patients realize relief from the burdensome symptoms of their disease earlier.”

The positive CHMP opinion of Cosentyx for nr-axSpA is based on efficacy and safety outcomes from the PREVENT Phase III study, which included 555 adults with active nr-axSpA with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs). Cosentyx met the primary endpoint, achieving statistically significant improvements versus placebo in the signs and symptoms of nr-axSpA, as measured by at least a 40% improvement in the Assessment of Spondyloarthritis International Society (ASAS40) response criteria in biologic-naïve individuals at Week 16[1].

About axSpA
AxSpA is a spectrum of long-term inflammatory disease characterized by chronic inflammatory back pain[6,7]. 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[9-11].

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[12].

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 “CHMP positive opinion,” “step forward,” “commitment,” “paves way,” “expectations,”“can,” “will,” “plan,” “may,” “could,” “would,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for Cosentyx, or regarding potential future revenues from Cosentyx. 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 Cosentyx 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 Cosentyx will be commercially successful in the future. In particular, our expectations regarding Cosentyx 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 www.novartis.com.

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References

1. Novartis data on file. September 2019
2. 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: November 2019].
3. 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.
4. 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.
5. 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.
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. Girolomoni G, et al. Psoriasis: rationale for targeting interleukin-17. *Br J Dermatol* 2012;167:717–724.
10. Sieper J, et al. The IL-23–IL-17 pathway as a therapeutic target in axial spondyloarthritis. Nat Rev Rheumatol 2019; 15:747–757.
11. 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
12. Data on file. COSENTYX Access. Novartis Pharmaceuticals Corp; May 2019

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