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MEDIA UPDATE • MEDIA UPDATE • MEDIA UPDATE

Novartis Cosentyx® builds on its axSpA leadership with US label update for dosing flexibility in ankylosing spondylitis

- *New Cosentyx® (secukinumab) US label to include 300 mg up-titration option is based on Phase III MEASURE 3 study results in ankylosing spondylitis (AS)[1]*
- *Label update provides clinicians with greater choice for their patients, based on clinical response to treatment*
- *Novartis has submitted to FDA and EMA for approval in non-radiographic axial spondyloarthritis (nr-axSpA)[2,3]; potentially providing patients with a treatment that addresses the axSpA disease spectrum*
- *Cosentyx is backed by 5-year sustained efficacy and safety data across AS, psoriatic arthritis and psoriasis, with over 300,000 patients treated worldwide[4-7]*

Basel, January 31, 2020 — Novartis, a leader in rheumatology and immuno-dermatology, announced today that the US Food and Drug Administration (FDA) has approved a label update for Cosentyx® (secukinumab) to include the option for up-titration to a 300 mg dose for adults with active ankylosing spondylitis (AS).

“This approval gives clinicians added flexibility to ensure patients are able to achieve the best response to treatment and experience full relief from the signs and symptoms of AS,” said Todd Fox, Global Head of Medical Affairs Immunology, Hepatology and Dermatology at Novartis. “It’s further encouraging news in our efforts to reimagine medicine across the axSpA disease spectrum.”

The FDA based the approval on data from MEASURE 3, a three-year study that assessed the efficacy and safety of two doses of Cosentyx, 300 mg and 150 mg, in patients with AS. Both doses met the primary efficacy endpoint of improving the signs and symptoms of AS. Long term data show that the response rate was greater in the 300 mg dose group, particularly among patients with previous anti-TNF exposure, compared with the recommended 150 mg dose. The safety profile was consistent with previous studies[1].

About axSpA
Axial spondyloarthritis (axSpA) is a spectrum of long-term inflammatory disease characterized by chronic inflammatory back pain[8]. The axSpA spectrum includes amongst other indications ankylosing spondylitis (AS), in which joint damage is generally visible on X-ray, and non-radiographic axial spondyloarthritis (nr-axSpA), in which joint damage is not visible on X-ray[8,9]. Both parts of the disease spectrum have a comparable symptom burden, including nocturnal waking caused by pain, morning stiffness, fatigue and functional disability[10]. If left

untreated, axSpA could impair activity, lead to lost work time and have a significant impact on quality of life[10].

About Cosentyx (secukinumab)
Cosentyx is the first and only fully-human biologic that directly inhibits interleukin-17A (IL-17A), a cornerstone cytokine involved in the inflammation and development of ankylosing spondylitis (AS), psoriasis (PsO) and psoriatic arthritis (PsA)[11-14].

Cosentyx is backed by robust clinical evidence, including 5-year data across PsO, PsA and AS, as well as data from real world evidence[4-6]. 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 its launch[7].

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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 more than 750 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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