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MEDIA UPDATE • MEDIA UPDATE • MEDIA UPDATE

Novartis receives approval for Cosentyx® label update in Europe to include dosing flexibility in ankylosing spondylitis

- *New Cosentyx® (secukinumab) label to include 300 mg up-titration option is informed by results from the Phase III MEASURE 3 study*[1]
- *Approval provides clinicians with greater choice for their patients, based on clinical response to treatment*[1]
- *News follows recent announcement of submission to EMA for new indication for non-radiographic axial spondyloarthritis (nr-axSpA), potentially providing patients with a treatment that addresses the complete axSpA disease spectrum*[2]
- *Cosentyx is an established brand supported by 5-year sustained efficacy and safety data across psoriatic arthritis, ankylosing spondylitis and psoriasis, with over 250,000 patients treated worldwide*[3-15]

Basel, October 24, 2019 – Novartis, a leader in rheumatology and immuno-dermatology, announced today that the European Commission (EC) has approved a label update for the up-titration of Cosentyx (secukinumab) to 300 mg for patients with active ankylosing spondylitis (AS).

The approval is based on data from MEASURE 3, a three-year study that explored the tolerability and efficacy of Cosentyx in patients with AS[1]. Response rates were 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].

“This approval gives rheumatologists more flexibility to ensure their patients are able to achieve the best response to treatment,” said Sam Khalil, Global Head of Medical Affairs Immunology, Hepatology and Dermatology at Novartis. “It further encourages our ongoing efforts to reimagine care to ensure all patients are able to experience full relief from the signs and symptoms of AS.”

About axSpA
Axial spondyloarthritis (axSpA) is a spectrum of long-term inflammatory disease characterized by chronic inflammatory back pain[16]. The axSpA disease spectrum includes ankylosing spondylitis (AS), in which joint damage is visible on x-ray, and non-radiographic axial spondyloarthritis (nr-axSpA), in which joint damage is not visible on x-ray[16]. Both parts of the disease spectrum have a comparable symptom burden, including nocturnal pain, fatigue, morning stiffness and functional disability[17]. If left untreated, axSpA can impair activity, lead to lost work time, and have a significant impact on quality of life[17].

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 psoriatic arthritis (PsA), psoriasis (PsO), and ankylosing spondylitis (AS)[18,19].

Cosentyx is backed by robust clinical evidence, including 5-year data across PsO, PsA and AS, as well as data from real world evidence[3-15]. 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 250,000 patients treated worldwide with Cosentyx since its launch[20].

Disclaimer

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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 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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