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IR & MEDIA UPDATE

Novartis Cosentyx® gains EU label update for first-of-its-kind MAXIMISE data in axial manifestations of psoriatic arthritis

- *Cosentyx® (secukinumab) is the first biologic with proven efficacy in all 6 key manifestations of psoriatic arthritis (PsA), and the only biologic with fast and lasting relief of axial manifestations of PsA in a dedicated trial[1,2,3].*
- *Up to two-thirds of patients with PsA suffer from axial manifestations[4]*
- *Phase IIIb MAXIMISE trial showed treatment with Cosentyx improved the signs and symptoms of axial manifestations of PsA as early as Week 4; response was maintained up to Week 52, with a consistently favorable safety profile[1]*
- *Cosentyx is an established brand, supported by long-term 5-year sustained efficacy and safety data across psoriasis, PsA and ankylosing spondyloarthritis (AS)[2,3,5-7], with 400,000+ patients treated worldwide since launch[8]*

Basel, February 26, 2021 — Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted the final opinion for a type II label variation for Cosentyx® (secukinumab) to include data for axial manifestations of psoriatic arthritis (PsA), from the first-of-its-kind MAXIMISE trial[1].

PsA patients with axial manifestations report higher disease burden with higher levels of pain, fatigue, morning stiffness, impairment of physical function, increased enthesitis count and higher levels of inflammatory markers[9,10]. They also report worse quality of life and/or work productivity[11].

Cosentyx is the only fully human interleukin (IL)-17A inhibitor to demonstrate efficacy and safety in a dedicated Phase IIIb study of axial manifestations in PsA[1]. It is the first biologic with proven efficacy in all six key manifestations of PsA including peripheral disease, enthesitis, dactylitis, skin psoriasis and nail psoriasis[2,3].

The label update reinforces Cosentyx leadership in rheumatology and immuno-dermatology, with plans to expand to 10 indications over the next 10 years.

About MAXIMISE
MAXIMISE is a 52-week, double-blind, randomized, placebo-controlled, Phase IIIb study to evaluate the efficacy and safety of Cosentyx® (secukinumab) in the management of axial manifestations of psoriatic arthritis (PsA). The trial included 485 patients with PsA and axial involvement diagnosed by the clinician, with spinal pain rated as >40/100 on a visual analog scale (VAS) and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) >4 despite a

trial of at least two non-steroidal anti-inflammatory drugs (NSAIDs). This study consisted of two treatment periods; a placebo-controlled period from baseline to Week 12 (treatment period 1) followed by an active treatment period from Week 12 to Week 52 (treatment period 2). At Week 12, placebo patients were re-randomized to subcutaneous Cosentyx 300 mg or 150 mg. Patients were treated with subcutaneous Cosentyx 300 mg or 150 mg given weekly for 4 weeks and every 4 weeks starting at Week 4. The primary endpoint was the proportion of patients achieving an Assessment of SpondyloArthritis International Society 20 (ASAS20) response with Cosentyx 300 mg at Week 12. The key secondary endpoint was ASAS20 response with Cosentyx 150 mg at Week 12 after superiority of Cosentyx 300 mg was established[1].

The trial met both its primary and key secondary endpoints with 62.9% and 66.3% vs 31.3% of patients treated with Cosentyx 300 mg and 150 mg vs. placebo achieving the primary endpoint, respectively. Rapid onset of improvement in the signs and symptoms of axial manifestations of PsA was seen as early as Week 4 and maintained up to Week 52. The safety profile was consistent to previous studies with no new safety signals[1].

About Cosentyx® (secukinumab)
Cosentyx is the first and only fully human biologic that directly inhibits interleukin (IL)-17A, a cornerstone cytokine involved in the inflammation and development of moderate-to-severe plaque psoriasis, psoriatic arthritis (PsA), ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)[13-15]. Cosentyx is the only biologic with proven efficacy in all six key manifestations of PsA[1-3].

Cosentyx is backed by more than 12 years of clinical experience and long-term five-year data across three indications of psoriasis, PsA and AS, as well as data from real-world evidence[16-21]. These data strengthen the unique position of Cosentyx as a rapid and long-lasting comprehensive treatment across axial spondyloarthritis, PsA and psoriatic disease, with more than 400,000 patients treated worldwide with Cosentyx since launch[8].

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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 media update as of this date and does not undertake any obligation to update any forward-looking statements contained in this media update as a result of new information, future events or otherwise.

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