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Cosentyx (secukinumab) Injection
Clinical Update

Clinical update: FDA Approved Cosentyx (secukinumab) for New Indication to Treat Active Non-Radiographic Axial Spondyloarthritis.
FDA approval date: June 16, 2020

Cosentyx is an interleukin-17A (IL-17A) inhibitor, an important cytokine responsible in inflammation and development of psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), ankylosing spondylitis (AS) and nr-axSpA. It is the first and only fully-human biologic that is capable of directly inhibiting IL-17A.
Cosentyx is an effective and is safe for long term treatment of moderate to severe plaque psoriasis (PsO), psoriatic arthritis (PsA) and ankylosing spondylitis (AS). More than 13 years of clinical studies has strengthen the unique position of cosentyx as a comprehensive treatment across axial spondyloarthritis, psoriatic arthritis and psoriatic disease, supported by more than 340,000 patients treated worldwide since launch.

Patients with active Non-Radiographic Axial Spondyloarthritis (nr-axSpA) were studied to investigate the efficacy and safety of cosentyx using PREVENT which is a two year randomized, double-blind, placebo-controlled Phase III study. 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. Of the 555 patients enrolled in the study, 501 (90%) 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).

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 52. Improvement was observed/seen in nr-axSpA patients who were treated with cosentyx in both load and without load arms compared tomplacebo- treated patients at week 16 in health-related quality of life as measured by the Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire (Least Squares mean change: Week 16: -3.5 and -3.6 vs -1.8, respectively).
At Week 16, patients treated with cosentyx showed greater improvement from baseline in the SF-36 physical component summary (PCS) score and in the mental component summary (MCS) score. The safety profile of Cosentyx in the PREVENT trial was shown to be consistent with previous clinical trials. No new safety signals were detected.