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Novartis announces FDA approval of Cosentyx for treatment of adult patients with AS and PsA

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Novartis announced today that the US Food and Drug Administration (FDA) has approved Cosentyx® (secukinumab) for two new indications - the treatment of adult patients with active ankylosing spondylitis (AS) and active psoriatic arthritis (PsA). AS and PsA are both life-long, painful and debilitating inflammatory diseases that affect the joints and/or spine. If not treated effectively, both conditions can lead to irreversible joint and/or spinal bone damage caused by years of inflammation.

With these new approvals, Cosentyx is now the first and only interleukin-17A (IL-17A) antagonist approved for AS, as well as moderate to severe plaque psoriasis and PsA, which impacts as many as 30% of patients with psoriasis. Cosentyx was approved for adult patients with moderate to severe plaque psoriasis in January 2015 and more than 13,000 patients with this disease in the US have already been treated with Cosentyx.

"We were inspired by patients to pursue new indications for AS and PsA, because these diseases can result in significant pain and impede the simplest of tasks in a person's daily life," said Christi Shaw, US Country Head, President at Novartis Corporation and Novartis Pharmaceuticals Corporation. "The approval of additional indications for Cosentyx represents an important milestone for AS and PsA patients, their caregivers, and their doctors."

The approvals are based on the efficacy and safety outcomes from two AS and two PsA placebo-controlled Phase III studies which included more than 1,500 adult patients with either AS or PsA. In the studies, Cosentyx met the primary endpoints achieving statistically significant improvements versus placebo in the signs and symptoms of AS and PsA, as measured by at least a 20% improvement in the Assessment of Spondyloarthritis International Society criteria (ASAS20) at Week 16 and a 20% reduction in the American College of Rheumatology (ACR20) response criteria at Week 24, respectively. ASAS20 and ACR20 are standard tools used to assess clinical improvement in AS and PsA. The safety profile is consistent across the three approved indications.

"Working directly with patients who have AS and PsA, I have seen firsthand the devastating impact the diseases can have," said Philip Mease, MD, director of rheumatology research at Swedish Medical Center, clinical professor at the University of Washington School of Medicine in Seattle and an investigator in the Cosentyx clinical trial program. "I welcome the addition of Cosentyx as a new treatment option for my patients with AS and PsA."

Source:
Novartis Pharmaceuticals Corporation