FDA’s Green Signal to Ixekizumab as the New Treatment for Active Ankylosing Spondylitis

NEWS

Pain Management

Recently, the Food and Drug Administration (FDA) approved a humanized interleukin-17A antagonist, Ixekizumab injection 80 mg/mL for the treatment of active spondylitis (AS), also well-known as radiographic axial spondyloarthritis (r-axSpA) in adults.

The first FDA- approval of Ixekizumab was for the treatment of moderate to severe plaque psoriasis in adults who are subjected for the systemic therapy or phototherapy and the second one was for the active psoriatic arthritis treatment.

This third approval was founded on data from 2 randomized, double-blind, placebo-controlled phase 3 studies, namely, COAST-V and COAST-W. The safety and efficacy of Ixekizumab were assessed among 657 patients with active AS who are biologic disease-modifying antirheumatic drug (bDMARD)-naïve and tumor necrosis factor (TNF) inhibitor-experienced. The primary endpoint for both the studies was the proportion of patients attaining an Assessment of Spondyloarthritis International Society 40 (ASAS40) response at 16th week.

Ixekizumab was found to be statistically significant and provided clinically meaningful improvements in the ASAS40 response compared to placebo in both the studies. In the COAST-V study, 48% of patients treated with Ixekizumab achieved an ASAS40 response versus 18% for placebo (P <.0001). The COAST-W study also demonstrated that 25% of Ixekizumab-treated patients achieved an ASAS40 response versus 13% for placebo (P <.05).

Also, Ixekizumab revealed statistically significant improvements in key secondary endpoints, comprising an ASAS20 response detected in 64% of Ixekizumab-treated patients in the COAST-V study versus 40% for placebo (P =.0015); and an ASAS20 response observed in 48% of Ixekizumb-treated patients in the COAST-W study versus 30% for placebo (P <.01). The safety profile was consistent with the safety profile observed in patients with psoriasis.

“Outcomes from the Phase 3 clinical trial program in AS showed that Ixekizumab provides pain relief, decreases inflammation and improves function in patients who had never been treated with a bDMARD along with those who formerly failed the TNF inhibitors,” as per Philip Mease, MD, Swedish Medical Center/Providence St. Joseph Health and University of Washington.

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