Video abstract transcript

Long-Term Safety and Efficacy of Ixekizumab in Patients With Axial Spondyloarthritis: 3-year Data From the COAST Program

doi.org/10.3899/jrheum.221022

Slide 1:

Hello, I'm Dr. Atul Deodhar, a Professor of Medicine and the Medical Director of rheumatology clinics at the Division of Arthritis & Rheumatic Diseases in Oregon Health & Science University, Portland. I would like to share with you the key highlights from our recent paper exploring the long-term safety and efficacy of ixekizumab in patients with axial spondyloarthritis, based on the 3-year data from the COAST program.

Slide 2:

Axial spondyloarthritis, or axSpA, is a chronic inflammatory disease and the primary goal of treatment is the maximization of long-term health-related quality of life.

Slide 3:

Ixekizumab is an IL-17A-targeting monoclonal antibody that is approved for the treatment of axial SpA. It has demonstrated efficacy in patients with axial SpA at 16 weeks, with improvements maintained through 2 years,3-6 and has a well-established safety profile7,8; however, data among patients who received at least one dose of ixekizumab through 3 years of the COAST program have not been reported until now.

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The COAST program consists of three originating studies: COAST-V, COAST-W, and COAST-X. Participants who completed all 52 weeks of any of the originating studies could enroll in a long-term extension program, COAST-Y.

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Patients treated with ixekizumab in their originating study continued at the same dose upon entering COAST-Y; COAST-X patients blinded to placebo were re-assigned to receive ixekizumab every 4 weeks.9 Following a 24-week lead-in period to COAST-Y, participants who achieved remission were entered into a randomized withdrawal-retreatment period, the details of which have been published previously.9 Patients who did not achieve remission continued to receive uninterrupted ixekizumab. Starting at Week 116 of the COAST program, patients receiving ixekizumab every 4 weeks with an inadequate response, based on investigator opinion, could have their dose escalated to treatment every 2 weeks.

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Safety outcomes reported in this analysis are shown here. The safety population consisted of patients who received at least one dose of ixekizumab over the 156-week program. Data are reported for the dosage that the patient was on at the time of adverse event occurrence.

Slide 7:

The efficacy outcomes reported in this analysis are shown here, with elements of disease status, function, and quality of life each assessed.1 The efficacy population included patients who received at least 1 dose of ixekizumab either every 4 or every 2 weeks

Deodhar et al. J Rheumatol 2023. doi.org/10.3899/jrheum.221022

through 156 weeks; patients receiving ixekizumab every 4 weeks were excluded if they had their dose escalated to treatment every 2 weeks.

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Overall, the safety profile of ixekizumab through 3 years was consistent with what has been previously reported.

Slide 9:

There were no unexpected safety concerns and treatment-emergent adverse events were generally mild or moderate in severity. Adverse events leading to discontinuation were low and remained in line with what has been reported previously.

Slide 10:

The incidence rates of selected adverse events of interest are shown here. Of these, injection-site reactions were most frequent, the majority of which were mild or moderate in severity. Incidence of serious infections and herpes zoster were low and there were no recorded cases of systemic candidiasis. Rates of IBD, or inflammatory bowel disease, were low and within the expected range for such a population. There were no [increases] in serious infections or IBD events over time.

Slide 11:

Moving over to efficacy, here you can see the ASDAS status at Week 156 among patients who received at least 1 dose of ixekizumab every 4 weeks and did not have their dose escalated, shown by treatment arm and by originating study. Please note that these are ‘as observed' data.

Across all of the study populations, of patients who received ixekizumab every 4 weeks in their originating study as well as in COAST-Y, 39-75% achieved either ASDAS inactive disease or ASDAS low disease activity at Week 156.

Slide 12:

Here we have the proportion of patients from the COAST-V originating study who achieved ASDAS low disease activity, defined as less than 2.1, over the full 156-week period. We're showing both the non-responder imputation and ‘as observed’ data, for completeness. The majority of patients from COAST-V achieved an ASDAS of less than 2.1 by Week 52, and this response was sustained through Week 156. Similar figures can be found in the manuscript for the patient populations of the other originating studies, as well for the different study end points, and I encourage you to take a look.

Slide 13:

Across all study populations, improvements in clinical efficacy outcomes were sustained through the 3-year program and were consistent with what has been published previously.

Slide 14:

In summary, this analysis of patients with axSpA in the COAST program demonstrated that the safety profile of ixekizumab is consistent with its established long-term safety profile. Long-term ixekizumab treatment provided sustained clinically important improvement through 156 weeks. Thank you.