PSORIASIS

IMMUNOGENICITY OF SECUKINUMAB, A FULLY HUMAN ANTI-INTERLEUKIN-17A MONOCLONAL ANTIBODY, IN PATIENTS WITH PSORIASIS, PSORIATIC ARTHRITIS, AND ANKYLOSING SPONDYLITIS DURING A 52-WEEK TREATMENT PERIOD

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Introduction: Secukinumab, a fully human monoclonal antibody that selectively targets IL-17A, is efficacious for the treatment of psoriasis (PsO), psoriatic arthritis (PsA), and ankylosing spondylitis (AS). Biologic therapies may be associated with immunogenicity, and treatment-emergent anti-drug antibodies (TE-ADA) may cause adverse events (AEs), such as hypersensitivity reactions, and affect drug pharmacokinetics and clinical response.

Objectives: To assess the immunogenicity of secukinumab in PsO, PsA, and AS patients treated for up to 52 weeks in phase 3
clinical trials.

Methods: Immunogenicity of patients with PsO (six trials), PsA (three trials), and AS (four trials) exposed to secukinumab was evaluated at baseline, Weeks 12 (PsO only), 16 (AS only), 24, and 52. TE-ADAs were defined as a positive anti-drug antibody signal in ≥1 post-treatment samples in patients negative at baseline. Positive samples were analyzed for drug-

neutralizing potential, impact of TE-ADA on secukinumab pharmacokinetics, immunogenicity-related AEs, and efficacy.

Results: Of N=2842 patients treated for PsO, N=1414 treated for PsA, and N=1163 treated for AS, 10 (0.35%), 5 (0.35%), and 8 (0.68%) developed TE-ADA, respectively. All but 1 PsA patient and 1 PsO patient were biologic naïve; 2 of 5 PsA and 1 of 8 AS patients received concomitant methotrexate, and 2 of 8 AS patients received concomitant sulfasalazine. Associations were not observed between TE-ADA and prior biologic use, secukinumab dose, frequency, or administration mode. Neutralizing antibodies were detected in 3/8 evaluable PsO patients, 1/5 PsA patients, and 0/8 AS patients with TE-ADA. Apart from partial response in one PsO patient, no TE-ADA was associated with loss of efficacy, alterations in pharmacokinetics, or AEs.

Conclusions: Immunogencity with secukinumab treatment up to 52 weeks across the multiple indications of PsO, PsA and AS was low (<1%). Neutralizing antibodies were not associated with AEs and generally not associated with diminished clinical responses.