PSORIASIS

SECUKINUMAB, A FULLY HUMAN ANTI-INTERLEUKIN-17A MONOCLONAL ANTIBODY, EXHIBITS LOW IMMUNOGENICITY IN PSORIASIS PATIENTS OVER 5 YEARS

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Introduction: Secukinumab, a fully human monoclonal antibody that selectively neutralizes IL-17A, a key cytokine involved in the development of psoriasis (PsO) and psoriatic arthritis (PsA), has shown long lasting efficacy and safety in the complete spectrum of psoriasis manifestations. Monoclonal antibody therapies may be associated with production of treatment-emergent anti-drug antibodies (TE-ADA) that can affect drug pharmacokinetics, diminish response, or cause hypersensitivity reactions. The incidence of immunogenicity of secukinumab in patients with moderate to severe plaque psoriasis has been assessed previously in the psoriasis phase 3 program as shown by TE-ADA in <1% patients up to 52 weeks.

Objective: To investigate the immunogenicity of secukinumab treatment up to 5 years in two phase III extension studies (NCT01640951 and NCT01365455) in patients with moderate to severe plaque psoriasis.

Material and Methods: Immunogenicity was evaluated up to Week 268 (5 years). TE-ADA were defined as positive anti-drug antibody signals detected in post-treatment samples from patients with negative baseline signals. Confirmed positive samples were further analyzed for their neutralizing potential.

Results: In total, 1821 patients entered the extension studies. Among patients receiving secukinumab and evaluated for anti-drug antibodies (n=1636), 32 developed TE-ADA, which resulted in an incidence of new TE-ADA cases below 1% per year. Neutralizing

antibodies were detected in 10/32 (31%) patients with TE-ADA. Half of ADA-positive cases were transient. Among pharmacokinetic samples measured at the times of immunogenicity determination (n=9992), 544 (5.4%) had secukinumab concentrations higher than the drug tolerance value of >53.8 µg/mL. There was no effect of TE-ADA, including neutralizing antibodies, on efficacy, safety, or pharmacokinetics of secukinumab.

Conclusions: The yearly secukinumab immunogenicity incidence over 5 years of treatment was consistently below 1% in patients with moderate to severe plaque psoriasis. Any TE-ADA, including neutralizing antibodies, were not associated with loss of secukinumab efficacy or with clinical concerns.