PSORIASIS

EFFICACY OF CONTINUOUS IXEKIZUMAB TREATMENT OVER 60 WEEKS IN SYSTEMIC-NAïVE PATIENTS AND AFTER SWITCHING FROM METHOTREXATE

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Background: Switching psoriasis treatment is a common practice and may improve outcomes in patients with inadequate response.

Objective: To evaluate efficacy of IXE over 60 weeks in systemic-naïve patients and those who switched from methotrexate (MTX) to IXE at Week24.

Methods: In this multicenter, open-label, parallel group, rater-blinded, Phase3b study (NCT02634801), 162 patients with moderate-to-severe psoriasis were randomized (1:1:1) to IXE (N=54), fumaric acid esters (FAE [N=54]), and MTX (N=54). At Week24, patients on IXE continued the same treatment; patients on FAE/MTX were allowed to switch to IXE. This analysis included patients who continued on IXE and who switched from MTX to IXE. The primary (Psoriasis Area and Severity Index [PASI]75) and secondary outcomes (PASI90/100/≤1/≤2/≤3, and Dermatology Life Quality Index [DLQI (0,1)]) were analyzed by Fisher's exact test with non-responder imputation.

Results: Of 162 randomized patients, 49 patients each on IXE and MTX arms completed 24-week treatment. At Week24, significantly higher response rates were observed in patients on IXE vs MTX (PASI75: 49[90.7%] vs 38[70.4%], p=0.0137; PASI90: 43[79.6%] vs 21[38.9%], p<0.0001; PASI100: 22[40.7%] vs 7[13.0%], p=0.002; PASI≤1: 40[74.1%] vs 16[29.6%], p<0.0001; PASI≤2: 46[85.2%] vs 26[48.1%], p<0.0001; PASI≤3: 47[87.0%] vs 32[59.3%], p=0.002; DLQI(0,1): 34[63.0%] vs 20[37.0%], p=0.012).
At Week24, 48 patients continued on IXE, and 31 patients on MTX switched to IXE. At Week60, patients who continued on IXE demonstrated sustained response rates (PASI100:

24[50.0%], PASI≤1: 38[79.2%], PASI≤2: 43[89.6%], PASI≤3: 45[93.8%]; DLQI (0,1): 36[75.0%]), and patients who switched to IXE demonstrated further improvements in response rates (PASI100: 13[41.9%], PASI≤1: 20[64.5%], PASI≤2: 25[80.6%], PASI≤3: 27[87.1%]; DLQI(0,1): 23[74.2%]). PASI≤1/≤2/≤3 results were independent of baseline values.

Conclusions: At Week60, continuous IXE therapy was highly efficacious. MTX-treated patients who switched to IXE after 24 weeks achieved higher levels of response at Week60 as compared with previous MTX treatment.