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Efficacy and safety of ixekizumab in real-world psoriasis patients: A retrospective unicentre study

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Background: Interleukin-17A inhibitor ixekizumab is indicated for the treatment of moderate to severe psoriasis. However, data related to ixekizumab in a real-world setting is currently quite limited.

Objective: To evaluate the efficacy and safety of ixekizumab in a cohort of real-word plaque psoriasis patients treated at our dermatology department.

Methods: A retrospective single-center analysis was performed. This study involved primary data from 31 patients.

Results: We included 25 men and 6 women. The mean ± SD age of the patients was 45.7 ± 13.9 years; and IMC 30.6 ± 10.35. Relevant comorbidities like hypertension, hyperlipidemia, chronic liver disease and VHC or VIH were presented in 10 (31%), 5 (16.1%), 2 (6.5%), 1 (3.2%) and 1 (3.2%) patients, respectively. Regarding previous treatment, 11 (35.5%) were naive patients whereas 20 (64.5%) of them had previously received another biologic treatment. Most patients (24/31) received treatment with ixekizumab 80 mg monthly without induction period. According to the as observed analysis, the percentage of patients achieving Psoriasis Area and Severity Index (PASI) 90 were 67.7% at 12 weeks, 75% at 24 weeks and 69.2% at 52 weeks. Regarding absolute values, the mean ± SD baseline score of PASI was 16.6 ± 6.9 and declined after ixekizumab administration to 2 ± 4.7 at 12 weeks, 2.4 ± 5.2 at 24 weeks, and 1.54 ± 2.6 at 52 weeks. Only 2 patients present mild to moderate adverse effects (mucocutaneous candidiasis).

Conclusions: According to our experience, ixekizumab is a highly effective and a safe treatment in real-world clinical practice.

Commercial disclosure: None identified.

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Long-term efficacy and safety of brodalumab in patients with or without metabolic syndrome

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Background: We assessed the long-term efficacy and safety of brodalumab, a fully human anti−interleukin-17 receptor A monoclonal antibody, in patients with moderate to severe plaque psoriasis, stratified by baseline metabolic syndrome (MetSyn) status.

Methods: In this post hoc analysis of the AMAGINE-1 trial, skin clearance was monitored by psoriasis area and severity index 75% improvement (PASI 75), PASI 90, and PASI 100 responses for patients who received brodalumab 210 mg every 2 weeks (q2w) continuously for 120 weeks (n = 83). Safety was summarized by exposure-adjusted treatment-emergent adverse event (TEAE) rates.

Results: At week 52, using observed data analysis in those with MetSyn (n = 27), 95.8%, 83.3%, and 62.5% achieved PASI 75, PASI 90, and PASI 100, respectively; corresponding percentages in those without MetSyn (n = 56) were 100%, 88.5%, and 78.8%, respectively. At week 120, using observed data analysis in those with and without MetSyn, 95.0% and 95.9% achieved PASI 75, respectively, 80.0% and 85.7% achieved PASI 90, respectively, and 75.0% and 73.5% achieved PASI 100, respectively. At week 120, using nonresponder imputation analysis in patients with MetSyn, 70.4%, 59.3%, and 55.6% achieved PASI 75, PASI 90, and PASI 100, respectively; corresponding percentages in patients without MetSyn were 83.9%, 75.0%, and 64.3%, respectively. Across all study years, the TEAE rates were 256.7 and 289.2 per 100 patient-years in those with and without MetSyn, respectively.

Conclusions: Efficacy responses through 120 weeks were somewhat higher in patients without MetSyn. Brodalumab was efficacious and well tolerated in patients with and without MetSyn.

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Efficacy and safety of long-term tildrakizumab for plaque psoriasis: 4-year results from reSURFACE 2

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Background: Anti−interleukin-23p19 monoclonal antibody tildrakizumab (TIL) is approved for treatment of moderate to severe plaque psoriasis.

Methods: The reSURFACE 2 3-part, double-blind, randomized, controlled, 52-week trial (NCT01729754) evaluated TIL 100 and 200 mg at week 0, week 4, and every 12 subsequent weeks and etanercept 50 mg to wk 28 in adults with moderate to severe chronic plaque psoriasis. Patients with ≥50% Psoriasis Area and Severity Index (PASI 50) improvement at wk 52 could enter the extension at the same TIL dose; PASI response, Physician's Global Assessment (PGA) response (0 or 1 with ≥2 reduction), and prespecified adverse event (AE) exposure-adjusted rates (EAR) are presented.

Results: Of 756 patients completing the base study, 731 entered the extension (2768.3 total patient-years [PY] exposure). At wk 52 (n = 376), 92%/70%/35% of patients receiving TIL 100 mg achieved PASI 75/90/100; at wk 200 (n = 322) 89%/64%/35% did. At wk 52 (n = 344), 89%/57%/29% of patients receiving TIL 200 mg achieved PASI 75/90/100; at wk 200 (n = 298), 89%/62%/30% did. At wk 200, 65%/66% receiving TIL 100/200 mg had a PGA response. By wk 200, 20.9% discontinued (most common reasons: patient withdrawal [7.5%], AEs [3.0%], loss to follow-up [2.9%]). Prespecified AE EAR (events/100 PY) during base and extension for TIL 100/200 mg (1513.3 PY/1404.7 PY) were 1.6/1.0 for severe infections, 0.7/0.7 for confirmed major adverse cardiac events (MACE), 0.6/0.1 for deaths, and 0.2/0.2 for drug-related hypersensitivities. The EAR for etanercept (n = 313) were 2.0, 0.7, and 0.0 for severe infections, MACE, and drug-related hypersensitivities, respectively.

Conclusions: PASI and PGA responses were maintained, with low prespecified AEs over 4-years of TIL treatment.

Commercial disclosure: The studies were funded by Merck Sharp & Dohme Corp, a subsidiary of Merck & Co, Kenilworth, New Jersey. Analyses were funded by Sun Pharmaceutical Industries, Princeton, New Jersey.

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Relationship of serum glucose to efficacy and safety of tildrakizumab treatment for psoriasis in patients with and without metabolic syndrome from reSURFACE 1 and reSURFACE 2

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Background: Tildrakizumab (TIL)—a high-affinity anti−interleukin-23p19 monoclonal antibody—is safe and effective in patients with plaque psoriasis and metabolic syndrome (MetS).

Methods: reSURFACE 1/2 (NCT01722331/NCT01729754) were 64/52-week 3-part, double-blind, randomized, controlled studies evaluating TIL 100 and 200 mg in adults with moderate to severe plaque psoriasis. Median percent improvement in Psoriasis Area and Severity Index (PASI) and treatment-emergent adverse events (TEAEs) were stratified by median baseline fasting serum glucose (≤94 vs >94 mg/dL) and MetS presence or absence.

Results: Of patients receiving TIL 100 and 200 mg, 79/362 (21.8%) and 67/327 (20.5%) had MetS, respectively. Mean (95% confidence interval [CI]) baseline fasting glucose was 117.8 (108.3, 127.3)/112.7 (105.0, 120.5) in MetS vs 93.1 (91.3, 94.9)/97.2 (94.1, 100.3) in non-MetS patients receiving TIL 100/200 mg, respectively. Slight increases in mean glucose at week 52 in MetS patients receiving 200 mg were due to outliers; glucose remained similar otherwise. For TIL 100/200 mg, mean (95% CI) PASI percent improvement at wk 52 was 91.1% (89.2, 93.1)/89.5% (87.2, 91.8), 90.3% (85.7, 94.9)/89.1% (84.9, 93.4), 89.5% (86.4, 92.7)/ 86.8% (83.9, 89.7), 87.0% (82.8, 91.1)/ 82.8% (76.1, 89.6) in glucose ≤94 non-MetS, glucose ≤94 MetS, glucose >94 non-MetS, and glucose >94 MetS patients, respectively. For TIL 100/200 mg, tier-1 TEAE rates per 100 patient-years were 10.0/10.3, 4.2/7.7, 8.0/8.5, and 9.7/4.1 for glucose ≤94 non-MetS, glucose ≤94 MetS, glucose >94 non-MetS, and glucose >94 MetS patients, respectively. No malignancies or worsening of diabetes occurred in patients with MetS.

Conclusions: There was no clinically meaningful relationship between baseline glucose, MetS, and TIL efficacy and safety.

Commercial disclosure: The studies were funded by Merck Sharp & Dohme Corp, a subsidiary of Merck & Co, Kenilworth, New Jersey. Analyses were funded by Sun Pharmaceutical Industries, Princeton, New Jersey.