Sustained and Improved Efficacy of Tildrakizumab from Week 28 to Week 52 in Treating Moderate-to-Severe Plaque Psoriasis

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INTRODUCTION
Psoriasis is a common, chronic, and immune-mediated skin disease, affecting 3.2% of the US population. Approximately 7.4 million people in the US have psoriasis.1 Psoriasis is characterized by painful, pruritic, well-demarcated, erythematous plaques with silver scale1,2, and often negatively impacts patients' overall health, quality of life, productivity, and interpersonal relationships.3 Tildrakizumab is a high-affinity, humanized, IgG1k anti-interleukin-23 monoclonal antibody designed to block interleukin-23 monomer activity.

METHODS
Both phase-3 trials randomized adult patients with moderate-to-severe plaque psoriasis to receive tildrakizumab 100 mg or tildrakizumab 200 mg at week 0, 4, then every 12 weeks, and used three-part study design

- Part 1 (week 0-12) randomized patients to: tildrakizumab 100 mg, tildrakizumab 200 mg, placebo, or etanercept 50mg (in reSURFACE 2)
- Part 2 (week 12-28) were re-randomized placebo patients to tildrakizumab;
- Part 3 (week 28-52, reSURFACE 1; week 28-52, reSURFACE 2) were re-randomized patients with Psoriasis Area and Severity Index (PASI) response ≥50% to the same, a higher or a lower dose of tildrakizumab, or placebo based on their week-28 PASI response

This analysis included only patients treated with the same dose of tildrakizumab as at week 28 and used week 28 PASI response data.

RESULTS
Overall, 352 patients on tildrakizumab 100 mg (mean: 69.9%) or 313 on tildrakizumab 200 mg (male: 67.1%; mean baseline age: 46.4 years) were included.

The proportions of patients achieving PASI 50, 75-90, and 75-100 at week 52 were 25.8%, 38.4%, 25.3%, and 10.5%, respectively for those on the 100 mg dose, and 24.6%, 24.3%, 19.5%, and 31.6% respectively for those on the 200 mg dose.

Week-52 PASI responses for patients treated with tildrakizumab 200 mg:
- Among patients achieving week-28 PASI 100 (n=77), 84.4% maintained PASI 100, 11.7% had PASI 90-99, 96.1% had PASI≤90, and all had PASI≤75 at week 52.
- Among patients achieving week-28 PASI 90-99 (n=76), 32.9% improved to PASI 100, 48.7% maintained PASI 90-99, and 17.1% had PASI 75-89 at week 52.
- Among patients achieving week-28 PASI 75-89 (n=61), 8.2% improved to PASI 100, 32.8% improved to PASI 90-99, and 39.3% maintained PASI 75-89 at week 52.
- Among patients achieving week-28 PASI 50-74 (n=99), 6.1% improved to PASI 100, 14.1% improved to PASI 90-99, 32.3% improved to PASI 75-89, and 41.4% maintained PASI 50-74 at week 52.
- Among patients achieving week-28 PASI 25-49 (n=37), 18.9% improved to PASI 100, 10.8% improved to PASI 90-99, 35.1% improved to PASI 75-89, and 24.3% maintained PASI 50-74 at week 52.

CONCLUSIONS
- Among patients with moderate-to-severe psoriasis treated with tildrakizumab 100 or 200 mg at weeks 0, 4, then every 12 weeks, those who achieved week-28 PASI≤50 and continued on the same dose had sustained or improved efficacy from week 28 through week 52.
- The majority patients who achieved week-28 PASI≤50 or PASI≤90 maintained PASI≤50 or PASI≤90 at week 52.
- More than half of partial responders (PASI 50-74) at week 28 were eventually achieved PASI≤50 and at least 1 in 5 achieved PASI≤90 at week 52.

REFERENCES
5. Stephen Rozzo, Alan Menter, and Kennedy Gordon were investigators of the phase 3 clinical trial for tildrakizumab (reSURFACE 1 and reSURFACE 2). Drs. Zhao, Lowry, Rozzo and Kennedy Gordon are employees of Sun Pharmaceutical Industries.

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DISCLOSURES
Dr. Stephen Rozzo, Jeffrey Crowley and Kennedy Gordon were investigators of the phase 3 clinical trial for tildrakizumab (reSURFACE 1 and reSURFACE 2). Drs. Zhao, Lowry, Rozzo and Kennedy Gordon are employees of Sun Pharmaceutical Industries.