Clearance of head and neck involvement in plaque psoriasis with tildrakizumab treatment in the phase 3 reSURFACE 1 study

Editor

Scalp, face and neck involvement in psoriasis negatively impact patient quality of life.[1–3] In the phase 3 double-blind, randomized, placebo-controlled reSURFACE 1 trial (NCT01722331), Psoriasis Area and Severity Index (PASI) response rates in patients with moderate to severe plaque psoriasis were high and durable following treatment with interleukin (IL)-23p19 inhibitor tildrakizumab, with acceptable safety.[4]

This post hoc reSURFACE 1 analysis evaluated scalp, head and neck psoriasis over 28 weeks in adult patients with moderate to severe chronic plaque psoriasis receiving tildrakizumab 100 mg or placebo. Patients were randomized 1:2:2 to subcutaneous placebo or tildrakizumab 100 or 200 mg, respectively, at weeks 0 and 4 and every 12 weeks thereafter. At week 12, patients receiving placebo were re-randomized to tildrakizumab 100 or 200 mg. Head involvement—including neck, scalp and face—was evaluated using PASI head component (PASIh) (range 0.0–7.2). To assess true clearance (PASIh = 0.0), values ≤0.5 were not rounded to 0. Efficacy was assessed for patients with baseline PASIh ≥ median baseline PASIh, ≥75th percentile of baseline PASIh and all patients using nonresponder imputation.

In total, 309 patients receiving tildrakizumab 100 mg and 154 receiving placebo were included. For 163 patients receiving tildrakizumab 100 mg with baseline PASIh ≥ 1.4, median (interquartile range [IQR]) baseline PASIh was 2.4 (1.8, 3.5); for 94 patients with baseline PASIh ≥ 2.4, median (IQR) baseline PASIh was 3.5 (2.8, 4.0). For all 309 patients receiving tildrakizumab 100 mg, median (IQR) baseline PASIh was 1.4 (0.8, 2.4). With placebo, median (IQR) baseline PASIh was 1.2 (0.6, 2.1). Among all patients, 23 (7.4%) receiving tildrakizumab 100 mg and 12 (7.8%) receiving placebo had baseline PASIh of 0.0.

For patients receiving tildrakizumab 100 mg with baseline PASIh ≥ 1.4, median (IQR) PASIh was 1.3 (0.6, 2.0) at week 4, 0.3 (0.0, 0.9) at week 12 and 0.3 (0.0, 1.2) at week 28. For patients with baseline PASIh ≥ 2.4, median (IQR) PASIh was 1.8 (1.0, 2.7) at week 4, 0.5 (0.0, 1.0) at week 12 and 0.3 (0.0, 1.2) at week 28. By week 12, 59 (36.2%) and 29 (30.9%) patients with baseline PASIh ≥ 1.4 and ≥2.4, respectively, achieved PASIh = 0.0 following tildrakizumab 100 mg treatment; 66 (40.5%) and 32 (34.0%) achieved PASIh = 0.0 by week 28 (Fig. 1).

Over 28 weeks, PASIh scores decreased rapidly for all 309 patients receiving tildrakizumab 100 mg (Fig. 2). At week 4, median (IQR) PASIh for all patients receiving tildrakizumab 100 mg was 0.5 (0.2, 1.4); by week 28, median (IQR) PASIh was 0.0 (0.0, 0.6). At weeks 12 and 28, 160 (20.8%) and 166 (21.5%) patients receiving tildrakizumab 100 mg, respectively, had PASIh = 0.0.

For patients receiving placebo, PASIh distribution at week 12 was similar to baseline (Fig. 1). Median (IQR) PASIh was 1.1 (0.3, 1.8) at week 12. The proportion of patients with PASIh = 0.0 on placebo remained steady; only 8.4%, 12.3% and 12.3% of patients had PASIh = 0.0 at week 4, 8 and 12, respectively. In total, 3 patients with baseline PASIh ≥ 1.4 receiving placebo had PASIh = 0 at week 12.

Tildrakizumab 100 mg treatment through 28 weeks resulted in rapid, progressive reduction in psoriasis scalp, head and neck involvement for patients with severe disease at baseline. PASIh comprehensively assesses face, neck and scalp, capturing high impact areas. Systemic IL-17 inhibitor ixekizumab and IL-23 inhibitor guselkumab were effective for scalp clearance; face and neck have not been assessed.[5,6] Tildrakizumab efficacy for scalp, head and neck clearance was similar to IL-17 inhibitor secukinumab and the tumour necrosis factor-α inhibitor adalimumab.[7–9] A phase 3b study of tildrakizumab 100 mg for scalp psoriasis is underway.

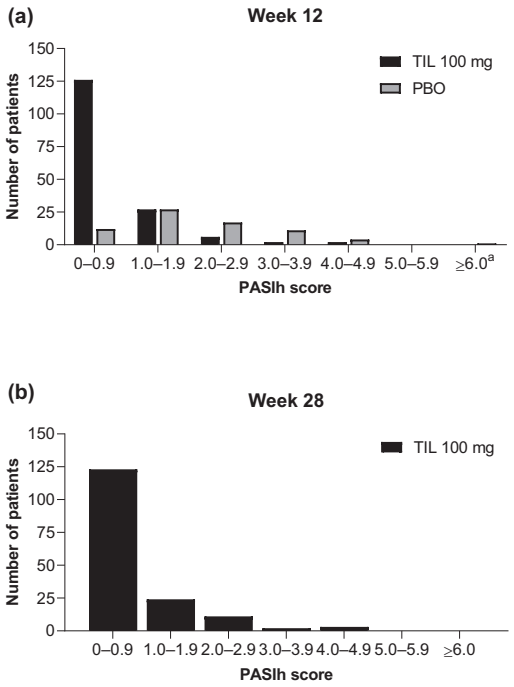

Figure 1 Distribution of PASIh scores of patients with baseline PASIh scores ≥ 1.4 at (a) week 12 and (b) week 28. Median baseline PASIh score was 1.4 for TIL 100 mg and 1.2 for PBO. TIL 100 mg, $n = 163$; PBO, $n = 72$. [a]$n = 1$. PBO-randomized patients received PBO to week 12, followed by TIL 100 or 200 mg to week 28. PASIh, Psoriasis Area and Severity Index head component; PBO, placebo; TIL, tildrakizumab.

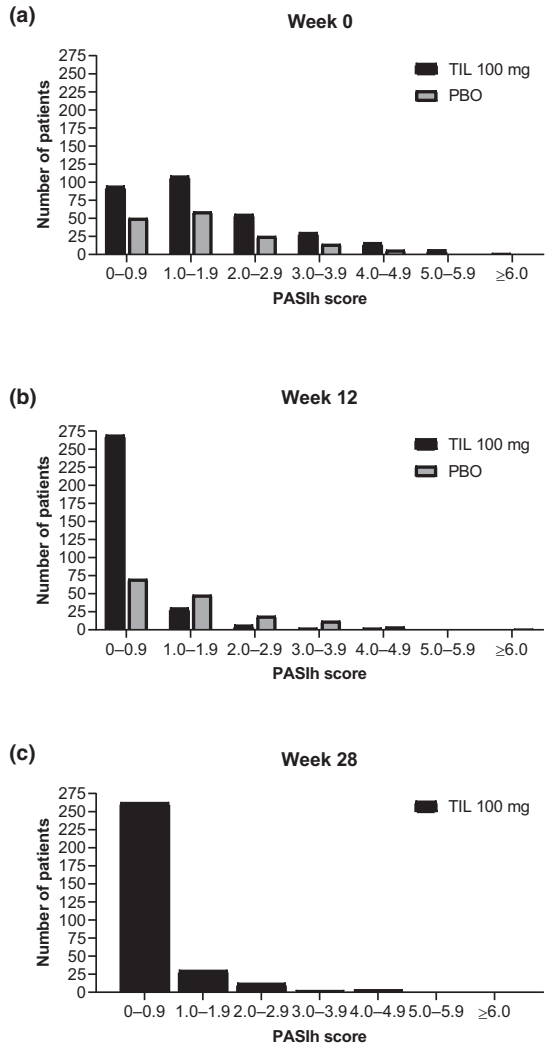

Figure 2 Distribution of PASIh scores of all patients receiving tildrakizumab 100 mg or placebo at (a) week 0, (b) week 12 and (c) week 28. TIL 100 mg, $n = 309$; PBO, $n = 154$. PBO randomized patients received PBO to week 12, followed by TIL 100 or 200 mg to week 28. PASIh, Psoriasis Area and Severity Index head component; PBO, placebo; TIL, tildrakizumab.

Conflicts of interest

MAM has received grants and/or honoraria as a consultant, investigator and/or speaker for Abbott Labs, AbbVie, Amgen, Anacor, Boehringer Ingelheim, Celgene, Eli Lilly and Co., Janssen Biotech, LEO Pharma, Merck & Co., Novartis, Sienna, and UCB; and has been on an advisory board for AbbVie, Amgen, Boehringer Ingelheim, Eli Lilly and Co., Janssen Biotech, LEO Pharma, and Sienna. GJM has received grants and/or honoraria as an investigator and/or speaker for Astellas Pharma US; Janssen Pharmaceuticals; Regeneron Pharmaceuticals; Merck & Co.; Eli Lilly and Co.; AbbVie; Pfizer; Demira; Bristol-Myers Squibb; UCB; Qurient; Sun Pharmaceutical Industries, Inc.; ChemoCentryx; Galderma Research & Development; Sanofi Genzyme; and Kiniksa Pharmaceuticals; and may have stock in Valeant Pharmaceuticals North America and Astellas Pharma US. HG has received honoraria as a member of an advisory board and/or speaker from Aqua, Galderma, Ortho Dermatologics and Pfizer. AMM is an employee of Sun Pharmaceutical Industries, Inc., and has individual shares in Johnson and Johnson and as part of retirement account/mutual funds. JP has served as statistical consultant for Sun Pharmaceutical Industries, Inc., and is a statistical consultant for Kyowa Kirin Pharmaceutical Development. SJR and DD are employees of Sun Pharmaceutical Industries, Inc. AG has been an investigator for Sun Pharmaceutical Industries, Inc.

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Light-based therapies and scar sarcoidosis

Editor

Scar sarcoidosis is characterized by the infiltration of non-caseating sarcoidal granulomas in surgical scars and other sorts of trauma.[1–3] Changing scars due to sarcoidosis might indicate a disease exacerbation. They are of prognostic relevance and necessitate a systemic evaluation.[4]

We report on an 86-year-old woman with disfiguring skin lesions on her face, referred to us in spring 2017. Her medical history was clear except for an arterial hypertension and a bilateral hilar and peribronchial

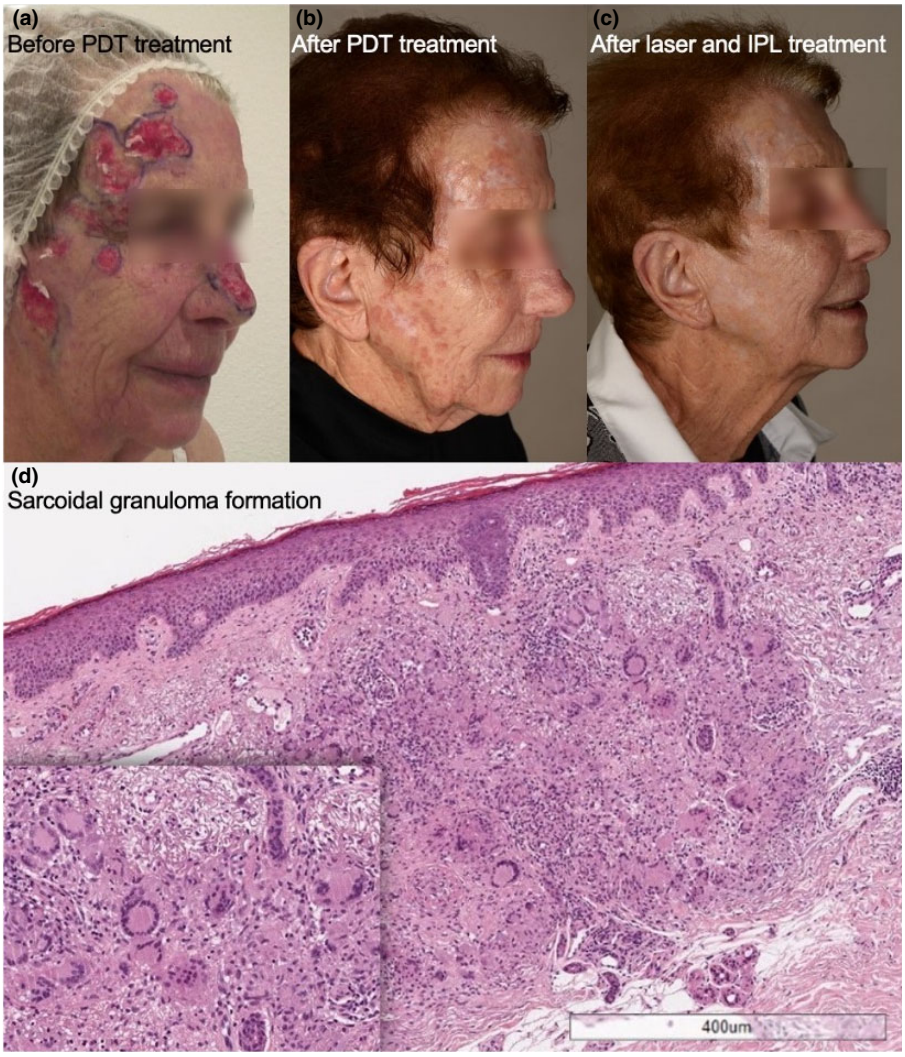

Figure 1 (a) Clinical picture of the patient's face before PDT. (b) Clinical picture of the patient's face after PDT. (c) Clinical picture after treatment with long-pulsed Nd:YAG 1064-nm laser and IPL. (d) Skin biopsy with sarcoidal granuloma formation. Haematoxylin and eosin.

