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Tildrakizumab significantly improves clinical outcomes in patients with psoriasis in high impact areas: 52-week interim data of the phase IV ZODIPSO study

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Introduction & Objectives:

Psoriasis in high-impact areas, including the scalp, nail, palmoplantar, and genital regions, has both physical and emotional impacts, affecting patients' wellbeing. These locations are typically difficult-to-treat and require specific management, leading to a recent consensus to reclassify the disease as severe when they are involved. This interim data evaluates the effectiveness and safety of tildrakizumab, an interleukin-23p19 inhibitor in routine care among patients with psoriasis affecting one or more high-impact areas.

Materials & Methods:

The ZODIPSO study is an ongoing 52-week, phase IV observational multicentric study in France, involving adult patients with moderate-to-severe plaque psoriasis affecting at least one of the following areas: scalp, nails, palms, and/or genital regions, treated with tildrakizumab. The decision to initiate treatment with tildrakizumab was made during routine clinical care, according to the summary of product characteristics. The study protocol was reviewed and approved by the concerned committees for all participating sites. Effectiveness outcomes included improvement in patients' Psoriasis Area and Severity Index (PASI) score and specific scores for each localization, such as the Psoriasis Scalp Severity Index (PSSI), the scalp Physician's Global Assessment (s-PGA), the modified Nail Psoriasis Severity Index (mNAPSI), the static PGA of Genitalia (sPGA-G), the Palmoplantar Psoriasis Area and Severity Index (PP-PASI) and the palmoplantar PGA (PP-PGA). Dermatology Life Quality Index (DLQI) measured patient quality of life. In these interim results, 122 patients were included, with 89 followed until 52 weeks.

Results:

A total of 122 patients were included (58.2% male, mean [SD] age of 51.3 [16.4] years). 54.1%, 72.1%, 40.2%, and 23.8% of patients had nail, scalp, genital, and palmoplantar psoriasis at baseline, respectively. The mean [SD] PASI decreased from 12.4 [9.4] at baseline to 1.4 [3.3] at week 52 ($p<0.001$). Among patients with nail psoriasis (n=66), the mean [SD] mNAPSI decreased from 48.9 [32.9] at baseline to 20.1 [23.2] at week 52 ($p<0.001$). In patients with scalp psoriasis (n=88), the mean [SD] PSSI significantly reduced from 24.5 [16.4] at baseline to 3.1 [6.9] at week 52. The proportion of patients with s-PGA of 0 or 1 increased from 13.6% at baseline to 69,4% and 83.8% at week 28 and 52, respectively. Regarding patients with genital psoriasis (n=49), the percentage of patients with sPGA-

G=0/1 increased significantly from 12,2% at baseline to 75% and 83.7% at weeks 28 and 52, respectively. Finally, in patients with palmoplantar psoriasis (n=29), the mean [SD] PP-PASI decreased from 10.8 [10.1] at baseline to 3.1 [5.0] at week 52. Similarly to scores in the different topographies, there was also an improvement in DLQI, which decreased from a mean score of 10.8 [7.0] at baseline to 3.4 [4.8] at week 52. No unexpected safety findings were reported during the study and no patient had to discontinue the drug because of treatment-emergent AEs or serious AEs.

Conclusion:

Anti-IL-23p19 antibodies offer an effective and safe treatment option for plaque psoriasis, but there are limited data regarding their efficacy in patients with difficult-to-treat sites. Based on the data reported here, we conclude that tildrakizumab is highly effective in patients with psoriasis in high impact areas in routine clinical care.